

## Dealdoc

# Co-promotion agreement for Exenatide once-weekly

Amylin Pharmaceuticals Eli Lilly

Sep 19 2002

# Co-promotion agreement for Exenatide once-weekly

• Details

**Financials** 

<u>Termsheet</u>

• Filing Data

Contract

**Financials** 

**Termsheet** 

Not available.

**Details** 

Press Release

Companies:	Amylin Pharmaceuticals
	<u>Eli Lilly</u>
Announcement date:	Sep 19 2002
	Loan agreement for Exenatide once-weekly
	First amendment to development, supply, manufacturing, licensing,
	promotion, and loan agreement for Exenatide once-weekly
	Development, supply, manufacturing, licensing, promotion, and loan
	agreement for Exenatide once-weekly (terminated)
	Milestone conversion agreement for Exenatide once-weekly
	Amendment to co-promotion agreement in US
Related contracts:	Amendment to research and development agreement for Exenatide
	once-weekly
	Supply agreement for exenatide once weekly pen device
	Registration agreement for Exenatide once-weekly
	Equity agreement for Exenatide once-weekly
	Manufacturing agreement for Exenatide once weekly product
	Security agreement for Exenatide once weekly
	Loan agreement for Exenatide
	Supply agreement for weeky exenatide
	0 40 000
Announcement date:	Sep 19 2002
Start date:	Sep 19 2002
	Bigpharma
	Bigbiotech
Industry contars:	Pharmaceutical
Industry sectors:	
	Biotech
	Drug delivery
Therapy areas:	Metabolic » Diabetes
	Devices
Technology types:	Drug delivery » Parenteral » Injectable
reciniology types.	
	Small molecules
Deal components:	Co-promotion
Dod oompononto.	Promotion
	Phase III
Stages of development:	Formulation
	Worldwide
Geographic focus:	
	North America » United States

Amylin Pharmaceuticals

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#### **Press Release**

26 May 2011

Amylin Pharmaceuticals Obtains Temporary Restraining Order Against Eli Lilly

SAN DIEGO, May 26, 2011 /PRNewswire/ -- Amylin Pharmaceuticals, Inc. (NASDAQ: AMLN) ("Amylin" or "the Company") today announced that the United States District Court for the Southern District of California issued a temporary restraining order (TRO) against Eli Lilly and Company (NYSE: LLY) ("Lilly") relating to its litigation with respect to the Amylin / Lilly diabetes collaboration agreement.

The U.S. District Court restrained Lilly from proceeding with its plans to use the same sales force to sell both exenatide and Boehringer Ingelheim GmbH's competitive linagliptin. The court also enjoined Lilly from disclosing any confidential information about exenatide to any of its sales representatives or employees participating in the marketing, promotion or sale of linagliptin.

The complete order is being filed today on Amylin's Current Report on Form 8-K with the Securities and Exchange Commission.

In 2002, Amylin entered an alliance with Lilly for the global development and commercialization of exenatide, a medicine indicated as a first line treatment for type 2 diabetes that is currently marketed as BYETTA® (exenatide) injection. Exenatide is also the active ingredient in BYDUREON™ (exenatide extended-release for injectable suspension), a once-weekly version currently under review by the FDA.

About BYETTA® (exenatide) injection

BYETTA was the first glucagon-like peptide-1 (GLP-1) receptor agonist to be approved by the FDA for the treatment of type 2 diabetes. BYETTA exhibits many of the same effects as the human incretin hormone GLP-1. GLP-1 improves blood sugar after food intake through multiple effects that work in concert on the stomach, liver, pancreas and brain.

BYETTA is an injectable prescription medicine that may improve blood sugar (glucose) control in adults with type 2 diabetes mellitus, when used with a diet and exercise program. BYETTA is not insulin and should not be taken instead of insulin. BYETTA is not currently recommended to be taken with insulin. BYETTA is not for people with type 1 diabetes or people with diabetic ketoacidosis. BYETTA has not been studied in people who have pancreatitis.

BYETTA provides sustained A1C control and low incidence of hypoglycemia when used alone or in combination with metformin or a thiazolidinedione, with potential weight loss (BYETTA is not a weight-loss product). BYETTA was approved in the U.S. in April 2005 and in Europe in November 2006 and has been used by more than 1.8 million patients since its introduction. See important safety information below. Additional information about BYETTA is available at http://www.byetta.com/.

## Filing Data

Not available.

#### Contract

U.S. CO-PROMOTION AGREEMENT

BY AND BETWEEN

AMYLIN PHARMACEUTICALS, INC.

AND

ELI LILLY AND COMPANY

EFFECTIVE AS OF

**SEPTEMBER 19, 2002** 

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U.S. CO-PROMOTION AGREEMENT

This U.S. Co-Promotion Agreement (the "Agreement") is made effective as of the

19th day of September, 2002 (the "Effective Date") by and between Amylin

Pharmaceuticals, Inc. ("Amylin"), a Delaware corporation having its principal

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place of business at 9373 Towne Center Drive, Suite 250, San Diego, California,

92121,

and

Eli Lilly and Company, an Indiana corporation having its principal place of business at Lilly Corporate Center, Indianapolis, Indiana, 46285 ("Lilly").

#### **RECITALS**

1. Amylin is developing Product for the prevention and treatment of diabetes and obesity and potentially other indications. Pursuant to the terms of a Collaboration Agreement of even date herewith, Lilly and Amylin have agreed to cooperate in the development and marketing of Product.

 In furtherance of the goals of the Collaboration Agreement, the parties desire to enter into this agreement for the Co-Promotion of Product in the United States.

NOW THEREFORE, in consideration of the foregoing premises and the mutual covenants contained in this Agreement, the Parties agree as follows:

ARTICLE I

**DEFINITIONS** 

As used herein, the following terms shall have the meanings indicated:

"ADDITIONAL INDICATION" shall have the meaning provided in the Collaboration

Agreement.

"ADVERSE EVENT" OR "ADVERSE EXPERIENCE" shall have the meaning provided in the Collaboration Agreement.

"ADVERSE EVENT REPORT" shall have the meaning provided in the Collaboration Agreement.

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 $\hbox{"AFFILIATE" shall have the meaning provided in the Collaboration Agreement.}\\$ 

"AMYLIN DETAIL PERCENTAGE" shall mean the percentage of total Product Details to be delivered by Amylin in the Co-Promotion Territory, as determined from time to time by the JCC.

"AMYLIN MARK" shall have the meaning set forth in the Collaboration Agreement.

"AMYLIN SALES FORCE" has the meaning set forth in Section 2.2.

"ALTERNATE DELIVERY" shall have the meaning provided in the Collaboration Agreement. "APPLICABLE LAWS" shall have the meaning provided in the Collaboration

Agreement.

"COLLABORATION AGREEMENT" means the Collaboration Agreement between the Parties of even date herewith, as the same may be amended from time to time by the Parties.

"COMMERCIALIZATION PLAN" shall have the meaning provided in the Collaboration Agreement.

"COMMERCIALLY REASONABLE EFFORTS" shall have the meaning provided in the Collaboration Agreement.

"CO-PROMOTE" OR "CO-PROMOTION" means an arrangement between Amylin and Lilly in which unless otherwise agreed by the Parties: (i) Amylin is the registration holder for the Product; (ii) Amylin makes all decisions regarding pricing of the Product (iii) Amylin Manufactures or has Manufactured for it all Product sold (iv) Amylin makes and records all sales of Product; (v) Amylin distributes all Product by utilizing the agreed upon channels of distribution (vi) a single trademark is used in connection with the Product; (vii) both Parties promote and market the Product; and (viii) both names or logos of the Parties appear on the Product (to the extent permitted by Applicable Law).

"CO-PROMOTION TERRITORY" means the fifty (50) states of the United States of America, the District of Columbia and any territory, possession, or protectorate of the United States of America.

"CSO" means a contract sales organization in the business of providing sales

Details for pharmaceutical products.

"DETAILS" means a Primary Detail and/or a Secondary Detail.

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"EFFECTIVE DATE" means the date this Agreement was entered into as stated in the first paragraph of this Agreement.

"FDA" shall have the meaning provided in the Collaboration Agreement.

"FIRST PRIORITY PRODUCT" means a pharmaceutical product for which a sales representative is expected to present the uses and benefits as the first product discussed in each of his or her face-to-face meetings with health care professionals during which he or she presents the uses and benefits of pharmaceutical products.

"GOVERNMENTAL AUTHORITY" shall have the meaning provided in the Collaboration Agreement.

"INDICATION" shall have the meaning provided in the Collaboration Agreement.

"JOINT COMMERCIALIZATION COMMITTEE" OR "JCC" shall have the meaning provided in the Collaboration Agreement.

"LILLY DETAIL PERCENTAGE" shall mean the percentage of total Product Details to be delivered by Lilly in the Co-Promotion Territory, as determined from time to time by the JCC.

"LILLY GOOD PROMOTIONAL PRACTICE GUIDELINES" means the proprietary guidelines adopted from time to time by Lilly, based on its understanding of Applicable

Laws, regarding the promotion of a pharmaceutical products in the Co-Promotion

Territory.

"LILLY MARK" shall have the meaning set forth in the Collaboration Agreement.

"MANUFACTURE" OR "MANUFACTURING" OR "MANUFACTURED" shall have the meaning provided in the Collaboration Agreement.

"MARKETING APPROVAL" shall have the meaning provided in the Collaboration

Agreement, but for purposes of this Agreement shall relate only to the

Co-Promotion Territory.

"NDA" shall have the meaning provided in the Collaboration Agreement.

"PARTY OR PARTIES" shall have the meaning provided in the Collaboration Agreement.

"PRIMARY DETAILS" means promotion of Product to medical professionals by a sales representative with the product presentation occurring as the First Priority

Product or Second Priority Product.

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"PRODUCT" shall have the meaning provided in the Collaboration Agreement.

"PRODUCT COMPLAINT" shall have the meaning provided in the Collaboration

Promotion Related Activities expressly excludes conference or convention

Agreement.

"PRODUCT LAUNCH" shall have the meaning provided in the Collaboration Agreement.

"PROMOTION RELATED ACTIVITIES" means lunches, snacks, dinners, entertainment, or medically related gifts for health care professionals with prescribing authority used to promote Product to such persons. For purposes of this Agreement,

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participation, continuing medical education programs, grants, paid speaker programs, symposiums and entertainment.

"PROMOTIONAL MATERIALS" shall have the meaning provided in the Collaboration Agreement.

"PROMOTIONAL PLAN" shall mean an annual strategic plan for the Co-Promotion of the Product by Amylin and Lilly in the Co-Promotion Territory developed by the JCC as part of the Commercialization Plan.

"REGULATORY MATERIALS" shall have the meaning provided in the Collaboration Agreement.

"RELATED AGREEMENTS" shall have the meaning provided in the Collaboration Agreement.

"SAMPLES" mean quantities of Product given to authorized medical professionals for no or minimal consideration as part of the marketing, advertising and promotion of the Product.

"SECOND PRIORITY PRODUCT" means the second priority pharmaceutical product for which a sales representative is expected to present the uses and benefits after presenting the First Priority Product in his or her face-to-face meetings with health care professionals during which he or she presents the uses and benefits of pharmaceutical products.

"SECONDARY DETAILS" means promotion of Product to medical professionals by a sales representative that is not a Primary Detail.

"STEERING COMMITTEE" or "JSC" shall have the meaning set forth in the Collaboration Agreement.

"TARGETED PHYSICIANS" means those categories of health care professionals with prescribing authority selected from time to time by the JCC as professionals

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to which Primary Details are to be delivered by Amylin and/or Lilly sales

"THIRD PERSON" shall have the meaning provided in the Collaboration Agreement.

"TRAINING MATERIALS" means the items the JCC develops after the Effective Date to train persons to promote Product in the Co-Promotion Territory.

ARTICLE II

representatives.

CO-PROMOTION AND SALES FORCES

#### 2.1 PRODUCT PROMOTION.

Upon the terms and conditions set forth in this Agreement, Amylin hereby grants Lilly during the term of this Agreement the co-exclusive right with Amylin to promote and detail Product in the Co-Promotion Territory in accordance with the terms of this Agreement. The principal objective of the Parties hereunder is to maximize the commercialization of the Product in the Co-Promotion Territory. Following receipt of Marketing Approval in the Co-Promotion Territory, the Parties shall each use their Commercially Reasonable Efforts to promote Product in the Co-Promotion Territory and to fulfill their obligations under this Agreement. The Parties shall deploy each of their respective sales forces in an effort to promote the Product in the Co-Promotion Territory in accordance with the Commercialization Plan in effect from time to time, the directions of the JCC, and the terms of this Agreement. Prior to Product Launch, and thereafter or an annual basis, the JCC shall agree upon (i) the number of Details needed for the following year, (ii) the number of Details that must be made as First Priority Product, Second Priority Product or as a Secondary Detail, (iii) the Amylin Detail Percentage and the Lilly Detail Percentage, and (iv) the size of each party's Sales Force and Detail Position necessary to permit each party to fulfill its obligations under this Agreement. Notwithstanding the foregoing, unless the Parties agree otherwise, each Party will [...\*\*\*...] to the promotion of the product.

### 2.2 AMYLIN SALES FORCE.

Amylin will establish a sales force of sales representatives responsible for Co-Promoting Product in the Co-Promotion Territory with Lilly (the "Amylin Sales Force") under this Agreement.

(a) Qualifications for Members of the Amylin Sales Force. Amylin will be solely responsible for recruiting, hiring and maintaining the Amylin Sales Force \*CONFIDENTIAL TREATMENT REQUESTED

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in accordance with its standard procedures and the guidelines, if any, developed by the JCC.

(b) Number of Sales Representatives. Amylin will be responsible for providing the Amylin Detail Percentage of the Details determined by the JCC to

Force will detail Product in the Co-Promotion Territory to Targeted Physicians in accordance with the Promotion Plan and the strategies established by the JCC.

(c) Training. The JCC shall establish procedures for sales training and for preparation of Training Materials related to Product. Amylin will be responsible for general sales training of its sales representatives and will implement Product related sales training in accordance with the procedures

be needed to promote Product in the Co-Promotion Territory, and Amylin's Sales

(d) CSOs. Amylin may not employ a CSO to fulfill any of its product detail obligations in the Co-Promotion Territory without the prior consent of Lilly, not to be unreasonably withheld. In any event, Amylin may only use a CSO to fulfill some of its Product detail obligations in the Co-Promotion Territory if such CSO is reputable and Amylin can demonstrate to Lilly that such CSO has been integrated into Amylin's sales force and business practices in the Co-Promotion Territory.

#### 2.3 LILLY SALES FORCE.

established by the JCC.

Lilly will establish or designate a sales force of sales representatives, responsible for Co-Promoting Product in the Co-Promotion Territory with Amylin (the "Lilly Sales Force") under this Agreement.

- (a) Qualifications for Members of the Lilly Sales Force. Lilly will be solely responsible for recruiting hiring and/or maintaining the Lilly Sales Force in accordance with its standard procedures and the guidelines, if any, developed by the JCC.
- (b) Number of Sales Representatives. Lilly will be responsible for providing the Lilly Detail Percentage of the Details determined by the JCC to be needed to promote Product in the Co-Promotion Territory, and Lilly's Sales Force will detail Product in the Co-Promotion Territory to Targeted Physicians in accordance with the Promotion Plan and the strategies established by the JCC.
- (c) Training. The JCC shall establish procedures for sales training and for preparation of Training Materials related to Product. Lilly will be responsible for general sales training of its sales representatives and will implement Product related sales training in accordance with the procedures established by the JCC.

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- (d) CSOs. Lilly may not employ a CSO to fulfill any of its Product detail obligations in the Co-Promotion Territory without the consent of Amylin, not to be unreasonably with held. In any event Lilly may only use a CSO to fulfill Product detail obligations in the Co-Promotion Territory if such CSO is reputable and Lilly can demonstrate to Amylin that such CSO has been integrated into Lilly's sales force and business practice in the Co-Promotion Territory.
- 2.4 ALIGNMENT OF AMYLIN'S SALES TERRITORIES AND SALES DISTRICTS.
- (a) Sales Territories. The sales territories, sales districts, and sales regions for the Amylin Sales Force shall to the extent practicable be geographically aligned with Lilly's sales territories, sales districts and sales regions for Product in the Co-Promotion Territory at Product Launch. If Lilly changes its territories, sales districts or sales regions after Launch, Amylin shall in good faith consider the advantages of alignment with Lilly's Sales Force, but shall not be obligated to make any change. Amylin's Sales Force shall include representatives for each state, territory, possession and protectorate within the Co-Promotion Territory.
- (b) Compensation. Each Party will use its Commercially Reasonable

  Efforts to ensure that variable pay components of its compensation structure, including but not limited to incentives, for its sales force with responsibility for promoting Product are consistent with the detail position the Parties' have agreed upon for Product with such sales force. To facilitate the determination of the incentives, the JCC will work with the Parties to coordinate annual sales plans.
- 2.5. TRACKING OF DETAILS. [...\*\*\*...] The JCC shall establish reasonable procedures for monitoring of sales force activities to ensure that each Party is complying with its obligations under this Agreement, and each Party agrees to make available to the other such information as may reasonably be required in order for the other Party to monitor compliance with this Agreement. As provided in Section 2.1, the JCC shall annually agree upon the size of the Amylin and Lilly sales forces and Detail position necessary to permit Amylin to fulfill its obligation to provide the Amylin Detail Percentage and Lilly its obligation to provide the Lilly Detail Percentage.
- 2.6 RESPONSIBILITY FOR THE SALES FORCE. In implementing the obligations

contained in this Agreement, each Party shall have sole discretion as to the manner (which shall not be inconsistent with the Commercialization Plan, and provided that neither Party will utilize any Promotional Materials not approved by

#### \*CONFIDENTIAL TREATMENT REQUESTED

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the JCC) in which it promotes and Details (including any expenditure of funds in connection therewith) the Product in the Co-Promotion Territory.

Neither party shall distribute or have distributed any information that bears the name or logo of the other Party without the prior approval of the other through the Steering Committee or the JCC, which approval shall not be unreasonably withheld.

Each Party shall have sole authority and responsibility for recruiting, hiring, training, managing, compensating, subject to Section 2.4(b) (including paying for all benefits, wages, special incentives, workers' compensation, and employment taxes), disciplining, firing, and otherwise controlling the persons comprising its sales force and for paying for any and all costs associated with its sales force's efforts under the Agreement. Each Party will provide the day-to-day management of its sales force, including, without limitation, furnishing administrative support, financial resources, equipment, and supplies, monitoring detail reporting and Sample accounting; and assuring the Sales Force's understanding and compliance with this Agreement and Applicable Laws.

ARTICLE III

### COMMERCIALIZATION RESPONSIBILITIES

#### 3.1 COMMERCIALIZATION EFFORTS

(a) Commercialization Plan

The JCC will develop a promotional detailing plan ("Promotional Plan") as part of the Commercialization Plan. The Commercialization Plan (including the Promotional Plan) will include, but not be limited to the following activities and state the responsibilities of each Party with respect to the activity, and the sharing of costs for each activity:

- (i) Promotion Related Activities;
- (ii) Medical plans (Phase 3 clinical trials and investigator

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initiated studies);

- (iii) Publications;
- (iv) Journal and magazine advertisements; advertising regulatory fees, media production;
- (v) Health economics studies and activities;
- (vi) Patient marketing activities (direct to consumer advertising, patient education, direct patient marketing, direct mail, web site development and maintenance);
- (vii) Market research;

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(viii) Product Launch meetings, training materials and

Promotional Materials;

(ix) Public relations and community relations related to

Product consultantships;

- (x) Business to business programs such as setting up programs with pharmacy benefit managers, wholesalers and chain drug stores and other activities in managed care;
- (xi) "Peer to Peer" activities such as continuing medical education, speaker training, consultants, advisory

boards; and

- (xii) Symposia, conferences, trade shows and conventions, convention donations, convention exhibits, grants, educational materials, compassionate use product, indigent programs
- (b) Sales Force Activities. The Promotional Plan will set forth is reasonable detail all material matters related to sales force activities. Each Party will utilize its Commercially Reasonable Efforts consistent with its customary business practices and Applicable Laws to deploy its sales force to promote and detail the Product in the Co-Promotion Territory in accordance with the Promotional Plan.
- (c) Managed Payors. The JCC will determine the authority of each Party, if any, to detail or otherwise promote Product to any physicians or to any

contracting agents, medical directors, formulary decision makers, benefit managers, or administrators (even if such persons are health care professionals legally authorized to prescribe Product) of a managed care organization (e.g., health maintenance organization, prescription benefits manager, insurance company, or similar entity), government-funded insurance or medical program, or employer. Amylin shall be solely responsible for the pricing of Product and any discounts, rebates or other deviations from the established price. All Product promotion and contracting activities with managed care entities will be conducted by the Party or Parties designated by the JCC.

(d) Promotion Related Activities. As part of the efforts under this

Agreement, each Party, in accordance with the Commercialization Plan, may have
its Sales Force conduct Promotion Related Activities with the health care
professionals to whom it is required to detail Product, but only to the extent
such Promotion Related Activities are conducted in accordance with the Lilly
Good Promotional Practice Guidelines or the Amylin equivalent and the American
Medical Association's and PhRMA's related guidelines. Except pursuant to
procedures approved by the JCC, neither Party has authority independent of the
other Party, (i) to conduct any form of direct-to-consumer promotion related to
Product, (ii) to schedule or manage conference involvement pertaining to
Product, (iii) to establish or manage advisory boards and opinion leaders for
Product, (iv) to conduct or sponsor continuing medical education programs, paid

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speaker programs, or symposia related to Product, (v) provide grants; or (vi) take any other action that the JCC determines will require its direction. All of such matters will be conducted as provided by the Commercialization Plan.

(e) Compliance. Each Party agrees that all activities under this Agreement by it or on its behalf, including, but not limited to, training, detailing, Promotional Activities, record-keeping, collection of consumer data (if any), and sampling, will be done in compliance with the FDA-approved package insert and labeling of Product, the applicable Promotional Materials, the Lilly Good Promotional Practice Guidelines or the Amylin equivalent and all Applicable Laws. Amylin has been provided a copy of the United States Federal Trade Commission's Decision and Order for In the Matter of Eli Lilly and Company

(Docket No. C-4047) issued May 8, 2002, and relating to the protection of patient identifiable information and agrees to cooperate with Lilly with respect to such Decision and Order provided that Lilly shall have ultimate responsibility for compliance.

- (f) Sales Force Issues. Should either Party identify a sales representative or member of sales force management in the other Party's Sales Force that the Party believes is damaging relationships with health care professionals or damaging the Product brand, such Party shall promptly notify the other Party in writing of such belief and the basis therefore. Following such notification, the Parties shall meet to discuss such belief and basis. The Party, in response to the other Party's concerns about such individual, shall take such action as it deems reasonable in the situation.
- 3.2 DISTRIBUTION OF SAMPLES OF PRODUCT.
- (a) Rights. As part of the efforts under this Agreement, each Party's

  Sales Force will distribute Samples of Product to the health care professionals
  to whom it Details Product. The JCC will develop appropriate procedures for
  delivery of Samples and Sample accountability. Amylin will supply, and Lilly
  will obtain, all such Samples from Amylin. The quantity and type of Product
  Samples to be distributed by the Parties' Sales Forces will be part of the

  Commercialization Plan. Each Party shall use Samples strictly in accordance with
  the then current Commercial Plan and shall distribute Samples in full compliance
  with all Applicable Laws.
- (b) Sample Forecasts, Purchase Orders, and Delivery. The JCC will establish a procedure for forecasting Sample needs, ordering, and delivery of Samples.
- (c) Allocations. In the event in any month there is shortage of Samples, unless otherwise agreed by the Parties, available samples will be allocated in accordance with each Party's share of the detailing responsibility.

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(d) Lilly's Responsibilities for Samples. Lilly shall be solely responsible for the transport, storage, handling, and distribution (both to the Lilly Sales Force and to the health care professionals) of the Product Samples it obtains under this Section. Lilly will transport, store, handle, and

distribute all Samples in compliance with all Applicable Laws and with the procedures established by the JCC.

- (e) Amylin's Responsibilities for Samples. Amylin shall be solely responsible for the transport, storage, handling, and distribution (both to the Amylin Sales Force and to the health care professionals) of the Product Samples it distributes. Amylin will transport, store, handle, and distribute all Samples in compliance with all Applicable Laws and with the procedures established by the JCC.
- 3.3 USE AND DISTRIBUTION OF PROMOTIONAL MATERIALS.
- (a) Promotional Materials. All Promotional Materials will be developed, produced and provided to and utilized by the Parties in accordance with the directions of the JCC. Promotional Materials will be reviewed and approved before use by a Medical/Regulatory/Legal Team created by the JCC.
- (b) Lilly's Use and Distribution of Promotional Material. As part of its efforts under this Agreement, the Lilly Sales Force will use and, as applicable, distribute Promotional Materials to the health care professionals to whom it Details Product in accordance with the Commercialization Plan. The Promotional Materials will be used by Lilly only for purposes of this Agreement. Lilly will obtain all Promotional Materials from the Party responsible for obtaining Promotional Materials pursuant to the Commercialization Plan in the quantity and of the type required by the Commercialization Plan. Lilly agrees that it will not create any Promotional Materials except as authorized by the JCC. Lilly also agrees that it will not copy or alter in any manner (including rearranging, underlining, highlighting, recording notes, etc.) the Promotional Materials nor will it allow its Sales Force to use any such unauthorized, copied, or altered Promotional Materials.
- (c) Amylin Use and Distribution of Promotional Materials. As part of its efforts under this Agreement, the Amylin Sales Force will use and, as applicable, distribute Promotional Materials to the health care professionals to whom it Details Product in accordance with the Commercialization Plan. The Promotional Materials will be used by Amylin only for purposes of this Agreement. Amylin will obtain all Promotional Materials from the Party responsible for obtaining Promotional Materials pursuant to the Commercialization Plan in the quantity and of the type required by the

Commercialization Plan Amylin agrees that it will not create any Promotional Materials except as authorized by the JCC. Amylin also agrees that it will not copy or alter in any manner (including rearranging, underlining, highlighting,

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recording notes, etc.) the Promotional Materials nor will it allow its Sales

Force to use any such unauthorized, copied, or altered Promotional Materials.

(d) Order and Delivery Procedures. The JCC will establish a procedure

for forecasting Promotional Material needs, ordering, and delivery of

Promotional Materials.

(e) Allocation. If the Party responsible for supplying Promotional

Materials does not have a sufficient supply in inventory to satisfy requests for
any Promotional Materials, unless otherwise agreed by the Parties, the available
supply will be allocated in accordance with each Party's share of the detailing
responsibility.

#### 3.4 DISCONTINUATION OF MATERIALS AND SAMPLES.

If the Party responsible for Training Material, Promotional Material or Samples informs the JCC in writing that a Training Material, Promotional Material, or Sample may no longer be used or distributed, each Party agrees that it will not allow its Sales Force to use or distribute such Training Material, Promotional Material, or Sample after the no-use date identified by the responsible Party in its notice.

#### 3.5 DISCRETION REGARDING STRATEGY FOR SALES FORCE.

(a) Lilly Responsibilities. Lilly will employ the strategies developed by the JCC and set forth in the Promotional Plan regarding Product sampling, Promotional Materials, and Promotion Related Activities for the Lilly Sales Force, but Lilly agrees that all activities under this Agreement by it or on its behalf, including, but not limited to, training, detailing, Promotion Related Activities, record-keeping, and sampling, will be done in compliance with the FDA-approved package insert and labeling of Product, all Applicable Laws, the Lilly Good Promotional Practice Guidelines and applicable PhRMA marketing practices guidelines.

Lilly covenants that it will not promote Product for any use not approved by the FDA. Lilly also covenants that it will not knowingly make any false or

misleading representation to any health care professional or others regarding Product and that it will not make, except as contained in the Promotional Materials and the product's package insert and labeling, any representation, warranty, or guarantee with respect to the specifications, features, or capabilities of Product.

(b) Amylin Responsibilities. Amylin will employ the strategies developed by the JCC and set forth in the Promotional Plan regarding Product sampling, Promotional Materials, and Promotion Related Activities for the Amylin Sales Force, but Amylin agrees that all activities under this Agreement by it or on its behalf, including, but not limited to, training, detailing, Promotion Related

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Activities, record-keeping, and sampling, will be done in compliance with the FDA-approved package insert and labeling of Product, all Applicable Laws, the Lilly Good Promotional Practice Guidelines or Amylin equivalent, and applicable PhRMA marketing practices guidelines.

Amylin covenants that it will not promote Product for any use not approved by the FDA. Amylin also covenants that it will not knowingly make any false or misleading representation to any health care professional or others regarding Product and that it will not make, except as contained in the Promotional Materials and the product's package insert and labeling, any representation, warranty, or guarantee with respect to the specifications, features, or capabilities of Product.

#### 3.6 SALES FORCE MEETINGS.

The JCC will work together to coordinate the timing of sales force meetings and to determine whether and when sales force meetings regarding Product should be jointly or separately held by the Parties.

#### 3.7 PROMOTION OF OTHER PRODUCTS.

While this Agreement is in effect, each Party has the right to have its Product sales force detail other products in any detail positions not reserved by the Parties for Product.

#### 3.8 INFORMATION TECHNOLOGY FRAMEWORK.

To ensure efficient, timely and accurate communication of data and information

between the Parties regarding activities under the Agreement, each Party, at its cost and on a time frame to be agreed upon by the Parties, will have in place and maintain an appropriate information technology infrastructure that includes a sales force automation tool, knowledge management tool, secure connectivity for sharing Sample and call activity, call notes, voice mail and e-mail and the use of which, as contemplated by the Parties under this Agreement, will not infringe or violate a Third Person's intellectual property or privacy rights.

The Parties agree to work in good faith to create and implement processes and technological mechanisms to prevent the disclosure between the Amylin Sales Force and Lilly's sales forces of call notes and similar information, regarding Amylin or Lilly promoted products other than the Product.

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#### 3.9 INSURANCE COVERAGE.

Each Party will maintain, at its own expense, insurance coverage on its activities under this Agreement. Such insurance will be maintained with a reputable insurance carrier(s), and will include, without limitation, errors and omissions insurance and comprehensive general liability insurance for claims for damages arising from bodily injury (including death) and property damages arising out of acts or omissions of the Party under this Agreement. Such insurance will also be written on a per occurrence basis, except that the Party's comprehensive general liability and directors and officers liability insurance may be on a claims-made basis. In addition, such insurance will provide that the insurer will notify each Party at least thirty (30) days in advance of any cancellation or modification of such insurance coverage. Maintenance of such insurance coverage will not relieve either Party of any responsibility under this Agreement for damage in excess of insurance limits or otherwise. Upon a Party's written request, the other Party will promptly provide it with a certificate from the insurer(s) evidencing such insurance coverage. Each Party will also maintain, at its expense, workers' compensation and employer's insurance for its Sales Force.

#### 3.10 TRADEMARKS AND LOGOS.

Trademarks and logos used in connection with Product shall be governed by the terms of the Collaboration Agreement.

#### 3.11 MARKET INFORMATION.

Each Party will provide the other with all information that the disclosing party deems significant and relevant to the detailing and promotion of the Product within a reasonable time after such information becomes known to the party, provided such information is not received under a secrecy obligation.

#### 3.12 USE OF AFFILIATES.

A Party may sublicense or subcontract its rights or obligations under this

Agreement only with the approval of the Parties, not to be unreasonably

withheld, except that a Party may sublicense or subcontract to the extent

permitted under Section 9.2 of the Collaboration Agreement and may subcontract

its obligations under this Agreement to an Affiliate (but only for so long as

such person or entity remains an Affiliate). However, the Party is solely

responsible for the performance of its obligations under the Agreement whether

performed by itself or by others, including an Affiliate, and even if a Party

uses an Affiliate to assist it in performing any of its obligations under the

Agreement, the other Party will continue to look exclusively to that Party for

performance of such obligation.

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ARTICLE IV

#### PRODUCT SALES

Amylin will make and record all sales of Product in the Co-Promotion Territory. Amylin will manufacture, or have manufactured, Product and supply it to the market in the Co-Promotion Territory. Amylin will maintain all responsibility for returns, charge-backs, and rebates on such sales, and solely control distribution (except sampling by the Lilly Sales Force) and pricing of Product in the Co-Promotion Territory. Amylin, through its wholesalers and distribution system, shall have in the Co-Promotion Territory the sole right to (1) receive, accept and fill orders for Product, (2) distribute the Product to customers, (3) control invoicing, order processing and collection of accounts receivable for Product sales, and (4) record Product sales in its books of account. Amylin shall determine, and the Commercial Plan shall include, commercial terms and conditions with respect to the sale and distribution of Product, including matters such as the price at which the Product shall be sold and whether any

discounts, rebates or other deductions should be made, paid or allowed. Amylin shall arrange and be solely responsible for shipment, distribution and delivery of the Product.

- (a) Misdirected Orders. If, for any reason, Lilly receives orders for Product, Lilly shall forward such orders to Amylin (or if directed by Amylin to Amylin's wholesalers) as soon as practicable.
- (b) Product Returns. If any quantities of the Product are returned to

  Lilly, Lilly shall immediately notify Amylin and ship them to the facility

  designated by Amylin. Lilly, at its option, may advise the customer who made the
  return that the Product should have been returned to Amylin, but shall take no
  other actions with respect to the return without Amylin's consent. All returns
  of Samples used by the Lilly Sales Force shall first be returned to Lilly and
  Lilly shall then ship returned Samples to Amylin.

ARTICLE V

#### GOVERNANCE OF THE RELATIONSHIP

Governance of the activities contemplated by this Agreement shall be effected through the Steering Committee and Joint Commercialization Committee established pursuant to and in accordance with the terms of the Collaboration Agreement.

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ARTICLE VI

#### OTHER INDICATIONS AND PRODUCTS

#### 6.1 CO-PROMOTION FOR OTHER INDICATIONS.

If the Parties develop Compound for any Additional Indication as provided in the Collaboration Agreement, the Parties' rights to, and responsibilities for, the commercialization of such Additional Indication will be consistent with their respective rights to, and responsibilities for promoting Product as set forth in this Agreement. The JCC will establish the detail level, detail position, promotion message, promotion materials and additional promotional matters for each Additional Indication consistent with the terms of this Agreement.

6.2 ALTERNATE DELIVERY.

If the Parties develop Alternate Delivery for Product as provided in the Collaboration Agreement, the Parties' rights to, and responsibilities for, the commercialization of such Alternate Delivery Product will be consistent with the

respective rights to and responsibilities for promoting Product as set forth in this Agreement. The JCC will establish the detail level, detail position, promotion message, promotion materials and additional promotional matters for each Alternate Delivery Product consistent with the terms of this Agreement.

ARTICLE VII

FINANCIAL PROVISIONS

All matters related to the Parties' compensation for their respective services hereunder and right to reimbursement for expenses and other financial matters shall be as set forth in the Collaboration Agreement.

ARTICLE VIII

**REGULATORY MATTERS** 

8.1 REGULATORY COMPLIANCE.

The rights and obligations of the Parties with respect to regulatory matters shall be as set forth in the Collaboration Agreement.

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8.2 PRODUCT COMPLAINTS.

The JCC will establish appropriate procedures for handling and reporting of product complaints.

8.3 MEDICAL INQUIRIES.

The JCC will establish appropriate procedures for dealing with medical inquiries.

8.4 PRODUCT RECALL OR REMOVAL FROM THE MARKET IN THE CO-PROMOTION TERRITORY.

In the event that a governmental entity issues a request, directive, or order, or the Parties determine in accordance with the Collaboration Agreement to recall or remove from the market some or all of the Product distributed in the Co-Promotion Territory, Lilly will cooperate with Amylin in conducting such recall or market removal (and any subsequent investigation by Amylin into the cause of the recall or market removal) to the extent such recall or market removal involves Product Samples distributed by Lilly. Lilly will maintain, and make available to Amylin, accountability and traceability records on all Product Samples it purchases from Amylin so as to permit, if necessary, a recall, market removal, or field correction of such Samples.

ARTICLE IX

#### CONFIDENTIALITY

9.1 OBLIGATIONS. Each Party agrees to hold in confidence the other Party's Confidential Information in accordance with the terms of the Collaboration Agreement.

9.2 DISCLOSURE OF THE TERMS OF THE AGREEMENT. Neither Party shall disclose the terms of this Agreement or use the names of the other Party except to the extent permitted under the terms of the Collaboration Agreement.

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ARTICLE X

REPRESENTATIONS, WARRANTIES, AND DISCLAIMERS

10.1 NO DEBARMENT UNDER THE GENERIC DRUG ENFORCEMENT ACT OF 1992.

Each Party represents and warrants to the other Party that it is not debarred under the Generic Drug Enforcement Act of 1992 (the "GDE Act") and is in compliance with the provisions of the GDE Act. Each Party also covenants that, while this Agreement is in effect, it will comply with the GDE Act, will not become debarred under the GDE Act, and will not use in connection with this Agreement the services of any person or entity debarred under the GDE Act.

Finally, upon request by the other Party, a Party will certify its compliance with the GDE Act and this Section in writing to such other Party. If, at any time, a Party breaches a covenant under this Section, the breaching Party will immediately notify the other Party of such fact.

10.2 PRODUCT SAMPLES.

At the time Amylin delivers Product Samples to Lilly's carrier as described in Section 3.2, Amylin represents and warrants to Lilly that such Samples:

- (i) comply in all material respects with the specifications in the
- NDA for Product,
- (ii) comply in all material respects with the Federal Food, Drug, and

Cosmetic Act (21 U.S.C. Section 301 et seq.) and regulations

issued hereunder, both as amended from time to time ("FDCA"),

- (iii) are not products that have been adulterated or misbranded within
- the meaning set forth in FDCA and any state or local law or
- $regulation \ substantially \ similar \ to \ FDCA,$
- (iv) are products that may be introduced into interstate commerce,

and

(v) have been manufactured, packaged, stored, and shipped in conformity with all applicable current good manufacturing practices.

10.3 TRAINING MATERIALS AND PROMOTIONAL MATERIALS.

No employee or representative of a Party shall have any authority to bind or obligate the other Party to this Agreement for any sum or in any manner whatsoever, or to create or impose any contractual or other liability on the other Party without the other Party's authorized written approval. For all purposes, and notwithstanding any other provisions of this Agreement to the contrary, the legal

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relationship under this Agreement of the Parties shall be that of independent contractors. Each Party shall be responsible for ensuring that its Promotional Activities under this Agreement are in full compliance with all Applicable Laws, including without limitation applicable FDA regulations, and are consistent with the Marketing Approval and package insert.

10.4 DISCLAIMER OF IMPLIED WARRANTIES.

EXCEPT AS EXPRESSLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY OTHER REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, STATUTE, OR OTHERWISE, AND EACH PARTY SPECIFICALLY DISCLAIMS ANY AND ALL IMPLIED OR STATUTORY WARRANTIES INCLUDING WARRANTIES OF MERCHANTABILITY, OF FITNESS FOR A PARTICULAR PURPOSE, AND OF NON-INFRINGEMENT.

10.5 LIMITATION OF LIABILITY.

NEITHER PARTY WILL BE LIABLE TO THE OTHER PARTY FOR INDIRECT, INCIDENTAL,
CONSEQUENTIAL, OR SPECIAL DAMAGES INCLUDING, BUT NOT LIMITED TO, LOST PROFITS
ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY
NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. HOWEVER, NOTHING IN THIS SECTION IS
INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY
PARTY.

ARTICLE XI

**TERM AND TERMINATION** 

11.1 TERM.

Unless extended by the Parties or terminated earlier, this Agreement will be in effect from the Effective Date until termination or expiration of the Collaboration Agreement, at which time this Agreement shall be deemed terminated.

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ARTICLE XII

**GENERAL PROVISIONS** 

12.1 LEGAL COMPLIANCE.

Each Party will comply with all Applicable Laws in the performance of its obligations or the exercise of its rights hereunder.

12.2 ASSIGNMENT.

This Agreement may be assigned only as provided in the Collaboration Agreement.

12.3 INDEPENDENT CONTRACTORS.

It is understood and agreed that the Parties are independent contractors and are engaged in the operation of their own respective businesses, and neither Party is to be considered the agent of the other Party for any purpose whatsoever.

Neither Party will have any authority to enter into any contracts or assume any obligations for the other Party nor make any warranties or representations on behalf of that other Party.

12.4 GOVERNING LAW. This Agreement and all amendments, modifications, alterations, or supplements hereto, and the rights of the Parties hereunder, will be construed under and governed by the laws of the state of New York exclusive of its conflicts of laws principles.

12.5 ENTIRE AGREEMENT. This Agreement, including any exhibits or attachments attached hereto and the Related Agreements constitutes the entire agreement between Amylin and Lilly with respect to the subject matter hereof, and all previous or other negotiations, representations and understandings with respect to the subject matter hereof between Amylin and Lilly are superseded as of the Effective Date. This Agreement has been prepared jointly and will not be strictly construed against either Party.

12.6 SEVERABILITY. If a provision of this Agreement (or portion thereof) is held to be illegal, invalid, or unenforceable by a court of competent jurisdiction, the remaining provisions (and portions thereof) of the Agreement shall remain in

full force and effect. In addition, to the extent feasible and legally permissible, the court of competent jurisdiction will replace the illegal, invalid, or unenforceable provision of this Agreement with a valid provision that eliminates such violation while conforming as closely as possible to the original terms of this Agreement.

If a provision of this Agreement (or portion thereof) that is essential to the commercial purpose of this Agreement is held to be illegal, invalid, or

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unenforceable by a court of competent jurisdiction and such court cannot replace (either because such replacement is not feasible or not legally permissible) such provision with a valid provision that eliminates such violation while conforming as closely as possible to the original terms of this Agreement, the remaining provisions (and portions thereof) of the Agreement remain in full force and effect, but either Party may terminate the Agreement upon written notice to the other.

12.8 COUNTERPARTS. This Agreement may be executed in one or more counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument.

12.9 NOTICES. All notices, statements, and reports required to be given under this Agreement shall be given in the manner specified in the Collaboration Agreement.

12.10 WAIVER. The failure of either Party to enforce any provision of this

Agreement at any time will not be construed as a present or future waiver of
such provision or any other provision of this Agreement.

12.11 MODIFICATIONS. No amendment, waiver or modification of this Agreement will be valid or binding on either Party unless made in writing and signed by duly authorized representatives of both Parties.

12.12 HEADINGS. All headings and captions used in this Agreement are for convenience only, and are not intended to have any substantive effect.

12.13 NO OTHER LICENSES OR RIGHTS. Except as specifically provided for in this Agreement, neither Party grants, expressed or implied, any license or rights to the other Party.

12.14 FURTHER ACTIONS. Each Party agrees to execute, acknowledge, and deliver