

LillyUSA
SALES GOOD PROMOTIONAL PRACTICES
ELI LILLY AND COMPANY
UNSOLICITED QUESTIONS ON OFF-LABEL INFORMATION OR UNAPPROVED PRODUCTS
GPP 01-004

Objective: To provide sales personnel with a policy and procedures regarding how to handle unsolicited questions for off-label information or unapproved products in order to ensure compliance with all applicable laws, regulations, and company policies.

Scope: This GPP applies to all sales personnel and sales support personnel in LillyUSA and all sales activities that take place in the United States or with US Healthcare Professionals.

Policy Statement: It is the policy of Eli Lilly and Company to comply with FDA regulations that prohibit the promotion of any unapproved new product; or indication, dosage form, and/or dosing schedule for any marketed product, with any customer by sales and marketing personnel, or other Lilly personnel or representatives in a promotional context.

Definitions:

Healthcare Professional: A Healthcare Professional is defined as any physician, physician's assistant, nurse, nurse practitioner, diabetes nurse educator, clinical investigator, pharmacist, Pharmacy and Therapeutics Committee ("P&T") member, social worker, case worker, dietitian, office staff, or any individual involved in prescribing, P&T, access, formulary, purchasing and/or reimbursement decisions.

Off-label Information: Any information about a Lilly product that is not contained in or is not consistent with the package insert labeling approved by the FDA. Examples include, but are not limited to, indications, dosage forms, dosing schedules, combination therapy, and safety information.

Procedure:

Sales Personnel **MAY NOT**:

Proactively discuss, present, or promote information concerning unapproved new products or off-label information about approved products with any customer or health care professional.

However, Sales Personnel **MAY**:

Respond orally to unsolicited requests for pre-approval or off-label product information, but only if all of the conditions below are strictly observed:

- The response is made to a customer-generated, specific question. The question from the customer cannot be prompted in any manner
- If a broad, general question is posed, ask the customer to narrow the inquiry
- Do not get drawn into detailed discussions of an off-label use. Route detailed questions back to Lilly's Customer Service Group for a medical letter response
- Before you respond you must advise the customer that their question is about an OFF-LABEL or NOT APPROVED topic and if appropriate, remind them of that drug's FDA-authorized indication(s) and/or dosage and other relevant labeling information. Example: "You will note [drug name] is not indicated for _____; it is indicated for _____."
- If the HCP's specific request is covered in a Brand-approved verbatim, that response

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must be used. It is the responsibility of the sales force to know any specific Brand verbatims and instructions about how to handle unsolicited questions. Any Brand verbatims and instructions will be found on KM

- If a Brand verbatim or other instructions are not available and the sales force knows the answer, a reply specific to the question asked may be given, but cannot be promotional
- The reply must be made only to the individual asking the question; others should not be able to hear the conversation
- Sales personnel must not volunteer additional information except within approved labeling
- Add fair balance (safety information) if relevant
- Sales personnel must also offer the HCP the option of a medical letter request as a supplement to the representative's verbal response.

If there is no Brand verbatim and sales personnel does not know any other information related to the question, the sales force must request a medical letter to respond to the health care professional's unsolicited question.

Medical Letters can be requested by one of the following methods:

- a. Call Sales Services (1-800-222-INDY) to request that a medical letter response be sent to the requester;
- b. Request a Medical Letter response be sent to the requester in the customer call section of Premier Force.

Policy Owner: Director of Compliance for Sales

Effective Date: 1/15/04

Version 3

NOTE: If you are using a printed copy of this document, check that the version number is consistent with the current version number in KM.

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