Eli Lilly and Company
Lilly Corporate Center
Indianapolis, Indiana 46285
U.S.A.

VIA EDGAR

September 18, 2009

Mr. Jim B. Rosenberg
Senior Assistant Chief Accountant
Division of Corporate Finance
U.S. Securities and Exchange Commission
100 F Street, N.E.
Washington, D.C. 20549

Reference: Eli Lilly and Company
Form 10-K for the Fiscal year Ended December 31, 2008
File No. 001-06351

Dear Mr. Rosenberg:

Eli Lilly and Company (Lilly) submits this response to your letter of August 20, 2009 commenting on our Form 10-K for the year ended December 31, 2008. For ease of reference, we have repeated your comments prior to our responses.

Comment:

Item 1. Management's Discussion and Analysis of Financial Condition and Results of Operations Government Investigations and Related Litigation, page 40

1. Please tell us why, under SFAS 5, you did not accrue a liability for the EDPA investigation prior to settlement. Please tell us why you believe prior to settlement that a loss was not probable and/or estimable.

Response:

Every quarter, senior financial reporting management meet with our inside legal counsel (and outside legal counsel, if necessary) to review any potentially material legal matters to which the company is a party and to evaluate potential liabilities under SFAS 5 and necessary disclosures. During the course of the nearly 5-year investigation led by the U.S. Attorney for the Eastern District of Pennsylvania (EDPA)[1], the company carefully considered at the end of

[1] We refer throughout to the investigation as the EDPA investigation; however, over the course of the investigation the EDPA civil division was joined by the Medicaid Fraud Control Units of the participating states, and the EDPA criminal division was joined by the Office of Consumer Litigation of the DOJ.

each and every quarter what disclosures were appropriate and whether an accrual should be recorded. At all of these quarter ends prior to the third quarter of 2008 when the liability was recorded, the significant uncertainty around the scope of the investigation and its ultimate resolution led us to conclude that we did not have a probable and reasonably estimable loss at that time.

In March of 2004 the EDPA advised the company it was conducting this investigation, and our 2004 first quarter Form 10-Q stated the following: “It is possible that the outcome of the above matters could include criminal charges and fines and/or civil penalties. We cannot predict or determine the outcome of the above matters or reasonably estimate the amount or range of amounts of any fines or penalties that might result from an adverse outcome. It is possible, however, that an adverse outcome could have a material adverse impact on our consolidated financial position, liquidity, and results of operations.” Substantially this same language was included in each 10-Q and 10-K following the initial disclosure until the charge was recorded in the third quarter of 2008.

This investigation was initially a civil investigation. The government requested and the company provided a large quantity of documents and information over the course of the civil investigation. In late 2007, the EDPA issued the first of several criminal grand jury subpoenas to the company so the investigation became both civil and criminal. Our 2007 10-K stated: “In November 2007, we received a grand jury subpoena from the EDPA for a broad range of documents related to Zyprexa. A number of State Medicaid Fraud Control Units are coordinating with the EDPA in its investigation of any Medicaid-related claims relating to our marketing and promotion of Zyprexa.”

The investigation remained active during the summer and early fall of 2008, as the government continued to subpoena and call witnesses to the grand jury, and the company continued to address the multiple and varied requests of the EDPA. Witness testimony continued through early October 2008. The last document production was on October 6, 2008.

The EDPA and the company engaged in discussions about a potential resolution of the civil investigation during the latter half of 2007 but those discussions stalled after the commencement of the criminal investigation. There were periodic discussions during 2008; however, there was significant uncertainty through September 2008 as to whether a negotiated resolution was possible and, if so, under what terms. The investigation involved potential claims of certain federal agencies (TRICARE Management Activity, Office of Personnel Management, and Public Health Service entities) as well as the Medicaid-related claims of the states that were participating in the coordinated investigation. From Lilly’s perspective, it was essential that any negotiated settlement involve resolution of both the criminal and civil investigations, be on acceptable financial terms, contain acceptable corporate integrity agreement commitments, and achieve final resolution not only of the federal claims but also the related claims of a large number of states. If the company could not reach agreement on these matters, it was prepared to defend itself on the merits at trial. The company had defenses to the allegations the government might have asserted at trial, but the outcome of such a trial

would have been highly uncertain. During the time period prior to September 2008, given the significant uncertainty as a result of the matters noted above, we did not believe that a resolution was probable or reasonably estimable. As the discussions developed, we continually updated our assessment of the likely outcome of the litigation, and we believe we applied SFAS 5 correctly at each quarter. Our conclusions were discussed with Ernst & Young, our auditors each quarter and they agreed that, given the facts and circumstances, this liability was not probable and reasonably estimable until the third quarter of 2008.

In August 2008, the EDPA clarified its views on the key settlement terms. The company disagreed with the government's position but the parties negotiated actively through September and early October 2008. Among other things, there were significant differences between the company and the EDPA regarding the guilty plea terms, the amounts to be paid as part of the sentence, and the scope of the releases the company would get. On October 7, 2008, the EDPA and the company reached an agreement in principle on several key terms in the resolution, including the monetary payment amount, the nature and scope of the sentence to be imposed, and other essential terms. We also received at this time sufficient assurance that a settlement consistent with the agreement in principle would likely be acceptable to most or all of the coordinating states. At that time, we determined that the potential liability became both probable and estimable under FAS 5. After further consultation with internal and external counsel, we recorded a liability for $1.42 billion in our third quarter 2008 financial results based on our advanced negotiations to resolve the matter and our belief (later confirmed) that it was probable that we would reach a final settlement on substantially the terms of the agreement in principle.

After October 7, negotiations continued among the EDPA, Lilly, the relators, the relators' counsel and the 36 states (plus the District of Columbia) that ultimately participated in the settlement. In addition, the company engaged in negotiations with the HHS Office of Inspector General about the terms of the corporate integrity agreement. The final agreements with the federal government were reached in January 2009. The federal district court accepted the guilty plea in January 2009 and state agreements were subsequently signed.

As a result of the above facts and in consultation with our internal and external counsel, we believe our liability in this matter first became both probable and estimable at the time of the agreement in principle and in accordance with the subsequent event rules the charge was properly recorded in the third quarter of 2008.

Comment:

Item 2. Consolidated Financial Statements
Notes to Consolidated Financial Statements
Note 3. Acquisitions, page 57

2. Regarding the ImClone acquisition, please disclose the following information relating to the in-process research and development acquired for each individual material project:

- The fair value assigned.
- The significant appraisal assumptions, such as:
  - the period in which material net cash inflows are expected to commence; and
  - material anticipated changes from historical pricing, margins and expense levels
- The completeness, complexity and uniqueness at the acquisition date.
- The nature, timing and estimated costs of the efforts necessary to complete the project, and the anticipated completion date.
- The risks and uncertainties associated with completing development on schedule, and consequences if it is not completed timely.
- In subsequent periods, disclose the status of efforts to complete the project, and the impact of any delays on expected investment return, results of operations and financial condition.

Response:

In evaluating the extent of appropriate disclosure for acquired IPR&D, we considered the requirements and related discussion in the AICPA Practice Aid on IPR&D. The Practice Aid provides the disclosure requirements relative to acquired IPR&D from the GAAP literature, which are very limited. SFAS 2 requires disclosure of only the total R&D costs charged to expense. SFAS 141 requires disclosure of the amount of IPR&D acquired and written off in the period and the line item in the income statement in which the amounts written off are aggregated. We have met all these disclosure requirements. The Practice Aid also notes that the SEC has requested public registrants to disclose the information you have requested above. The Practice Aid further states “disclosures need to be provided only about items that are qualitatively or quantitatively material — individually or in the aggregate.” Further, it states that, “Disclosures about IPR&D should be considered in the context of the financial statements taken as a whole.” We considered all of these factors in determining the extent of disclosure that would be appropriate for this transaction.

The aggregate IPR&D charge of approximately $4.7 billion consisted of nine compounds. We evaluated the materiality of these compounds and disclosed the fair value assigned to the four that we considered to be material in Note 3 on page 58 of our Annual Report on Form 10-K as noted below:

> “All of the estimated fair value of the acquired IPR&D is attributable to oncology-related products in development, including $1.33 billion to line extensions for Erbitux. A significant portion (81 percent) of the remaining value of acquired IPR&D is attributable to two compounds in Phase III clinical testing and one compound in Phase II clinical testing, all targeted to treat various forms of cancers.”

The disclosure above addresses all but approximately $600 million of the $4.7 billion IPR&D charge. This remaining portion for which we did not provide specific disclosure consisted of the fair value of five different compounds, each individually insignificant, that were in earlier stages of development. We did not believe that these projects met the level of materiality that would require disclosure.

We specifically included the stage of development in the disclosure to give the users of the financial statements a reasonable understanding of the "completeness" of the projects at the acquisition date. Briefly, Phase I refers to early clinical testing on healthy volunteers to determine initial safety and tolerability; Phase II is small-scale testing on patients who have the target disease to determine if there is any initial evidence of efficacy and to continue to assess safety; and Phase III, or "registration trials", are large-scale trials designed to more persuasively determine if the compound is efficacious with limited side effects. The data accumulated in Phase III is necessary for submission to the FDA for regulatory review and a decision on whether or not to grant approval.

In determining our disclosure, we also considered that the drug candidates acquired pursuant to the ImClone acquisition would be managed similarly to our existing projects for internally developed compounds. Once acquired, these potential drugs became part of our larger portfolio of compounds, for which no disclosures are required beyond the total amount of R&D costs incurred. While the initial costs of purchasing rights to these compounds were significant, the ongoing costs of these individual projects are not material relative to our total spending on R&D, which exceeded $3.8 billion in 2008, and we specifically disclosed this fact in the second paragraph of Note 3. Regarding risks and timing of anticipated completion, we have historically not disclosed information relating to timing of development of specific compounds because of the significant uncertainty involved. Not only is there a relatively high risk of failure (data indicates that compounds in Phase I or earlier have less than a 20 percent chance of ultimately being approved for marketing, while the chance of success is approximately 20 – 25 percent for compounds in Phase II and 60 – 70 percent for Phase III), but there is also significant uncertainty regarding the timing of the regulatory review process. Our Form 10-K contains a discussion of the time required for drug development and the significant risks involved which applies to all projects in our development portfolio. We considered this disclosure to be sufficient when considering the relative immateriality of the acquired compounds to our portfolio as a whole.

Given this background, we believe that our disclosures are appropriate.

As requested, we acknowledge that:

- We are responsible for the adequacy and accuracy of the disclosure in our filing;
- Staff comments or changes to disclosure in response to staff comments do not foreclose the Commission from taking any action with respect to the filing; and
- Eli Lilly may not assert staff comments as a defense in any proceeding initiated by the Commission or any person under the federal securities laws of the United States.

If you have any questions about these responses or require additional information, please contact me at (317) 276-2024.

Sincerely,

/s/ Arnold C. Hanish
Arnold C. Hanish
Vice-President and Chief Accounting Officer
ELI LILLY AND COMPANY