

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

VIA EDGAR

July 13, 2016

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

Re: Eli Lilly and Company

Form 10-K for the Fiscal Year Ended December 31, 2015

Filed February 19, 2016 File Number 001-06351

Dear Mr. Rosenberg:

Eli Lilly and Company (Lilly) respectfully submits this response to your letter dated June 17, 2016 commenting on our Form 10-K for the year ended December 31, 2015. For ease of reference, we repeat your comments prior to our responses.

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Management's Discussion and Analysis

Application of Critical Accounting Policies

Revenue Recognition and Sales Return, Rebate, and Discount Accruals

Financial Statement Impact, page 50

1. Please refer to your response to our prior comment 1. You indicate that the percentage increase from 2013 to 2014 is largely due to new contracts that began on January 1, 2014 associated with your insulins portfolio and that these new contracts increased the amount of product sold; however, the discounts given in these new contracts were higher than your prior average discounts, causing the increase in your sales return, discounts, and rebate percentage. You do not attribute any impact to your gross margin in 2014 to these contracts in your disclosure on page 45. Please tell us why.

Response:

Our worldwide gross margin analysis in the "MD&A - Operating Results - 2014" section on page 45 states,

"Gross margin as a percent of total revenue was 74.9 percent in 2014, a decrease of 3.9 percentage points compared with 2013, driven primarily by lower sales of Cymbalta and Evista following U.S. patent expirations."

In our previous response, we cited increased discounts associated with the new insulin contracts in the U.S. as a cause of the increase in our sales return, discounts and rebate <u>percentage</u> from 2013 to 2014. In addition to the increased discounts associated with these new contracts, we increased our list prices of our insulin portfolio. The higher gross prices (list prices) and higher discounts did result in <u>slightly</u> lower net effective selling prices for the insulins in the U.S. in 2014 compared to 2013, but the impact of the insulins on our gross margin as a percent of total revenue was insignificant compared to the magnitude of the U.S. volume declines for Cymbalta[®] and Evista[®]. These two products previously contributed positively to our gross margin percentage, so the loss of revenue from the patent loss of these products was by far the largest contributor to our gross margin percentage decline in 2014.

Notes to the Consolidated Financial Statements

Note 18. Segment Information, page 101

- 2. We acknowledge your response to our prior comment 2. Please address the following in order to further clarify your response:
 - From your response and in particular exhibit A to your response, it appears that the Pharma Segment leaders as a group represent the Pharma segment manager. Please confirm that our understanding is correct.

Response:

The Pharma Segment leaders, including the Business Area leaders along with the leaders of the various Organizational Units are the key members of our Executive Committee (EC), who make recommendations for the Pharma Segment, primarily related to their Business Area or Organizational Unit, as applicable; however they do not operate in a decision-making capacity. Rather, the EC is used as a mechanism to provide input to the chief operating decision maker (CODM). The CODM is responsible for the key operating decisions (e.g., research and development and manufacturing) for the Pharma Segment, and therefore the CODM effectively functions as the Pharma Segment manager. We do not believe the Pharma Segment leaders as a group represent the Pharma Segment manager as they do not

have the ability to make key operating decisions around research and development (R&D) or manufacturing.

- You state in your response that there are no components within either of your operating segments that meet the criteria of ASC 280-10-50-1 to be reported separately. However, we note from page 8 in your response that the CODM receives revenue and contribution information for each of the four global Business Areas within the Pharma segment on a monthly basis in order to allocate resources and assess performance. This information includes comparisons of actual amounts against plan (budget) as well as compared to the prior year.
 - Provide us an analysis as to whether each of these four global Business Areas represents an operating segment. Address each of the criteria in ASC 280-10-50-1.

Response:

In our prior response on page 8, our statement that our CODM regularly reviews financial information to allocate resources and assess performance relates to the Pharma Segment in total (which includes the Pharma Segment Business Areas, Pharma Segment Organizational Units, and the supporting Organizational Units) and the Animal Health Segment in total. We did not intend it to be interpreted that the Pharma Segment Business Area contribution information is used to assess the performance of the Pharma Segment or allocate resources between the four Pharma Segment Business Areas. As noted in our original response, "the operating results for the Pharma Segment and Animal Health Segment are the main focus" when assessing the Company's business performance, making resource allocation and key operating decisions, and setting compensation measures using this financial information that is regularly reviewed.

As discussed in our previous response, the most critical decision within the Pharma Segment is the major resource allocation decisions on whether or not to advance a particular product through the R&D process. As discussed later in this response, the information used in making these R&D resource allocation decisions is accumulated and the CODM decides which programs are brought forward and which ones are not. These decisions are made irrespective of the Pharma Segment Business Area, and are focused on items such as the likelihood that a drug in development ultimately receives approval for marketing (probability of technical success or pTS) and the other factors discussed in our response below with respect to the Staff's question regarding the factors considered for R&D decisions. These processes are managed by the human pharmaceutical products R&D organization, headed by the Executive Vice President (EVP) - Science/Technology and President - Lilly Research Labs, and this information is shared with the CODM for his consideration and decision on the recommendations.

The other critical resource allocation decision within the Pharma Segment relates to manufacturing and includes capacity decisions, manufacturing investments, and sourcing decisions. Recommendations for these decisions are managed by the President - Manufacturing Operations who provides manufacturing related information to the CODM, however, the CODM is responsible for these manufacturing decisions.

Since the decisions referred to above are so critical to the entire Pharma Segment, all of the Pharma Segment information is needed in order for the CODM to allocate resources and assess performance, which we believe supports our conclusion that his decisions regarding resource allocation are made based upon what is best for the Pharma Segment as a whole and that performance is assessed at the operating segment level.

ASC 280-10-50-1 defines an operating segment as a component of a public entity that has all of the following characteristics:

- a. It engages in business activities from which it may earn revenues and incur expenses (including revenues and expenses relating to transactions with other components of the same public entity).
- b. Its operating results are regularly reviewed by the public entity's chief operating decision maker to make decisions about resources to be allocated to the segment and assess its performance.
- c. Its discrete financial information is available.

We believe that there are no components within our Pharma Segment that meet all three of the characteristics to be a separate operating segment as our CODM is making key operating decisions on resource allocation and assessing performance at the identified operating segment level. Due to the similarity in the three characteristics of an operating segment across our four Pharma Segment Business Areas, our analysis below relates to each of the four Pharma Segment Business Areas.

a. It engages in business activities from which it may earn revenues and incur expenses (including revenues and expenses relating to transactions with other components of the same public entity).

The Pharma Segment Business Areas represent our four pharmaceutical sales and marketing functions. Each Pharma Segment Business Area engages in business activities in which they may earn revenues and incur expenses. This characteristic is present.

b. Its operating results are regularly reviewed by the public entity's chief operating decision maker to make decisions about resources to be allocated to the segment and assess its performance.

As discussed in the introduction of this response and below, our CODM makes decisions about resources to be allocated and assesses the performance at the total Pharma Segment level rather than at the level of the individual Pharma Segment Business Areas.

During the monthly EC financial review process, our CODM regularly reviews the financial information listed below for the Pharma Segment.

- Consolidated income statements (which includes the Pharma Segment Business Areas revenue, direct expenses, and Business Area contribution along with the total operating expenses of the Pharma Segment Organizational Units and supporting Organizational Units) for month, quarter and/or year-to-date periods versus plan and the prior period
- Revenue results analyzing the price, rate and volume trends versus plan and prior period

Key operating and resource allocation decisions that are made by the CODM, including significant R&D and manufacturing decisions, as discussed earlier in our response, are focused on considering what project or product would be best for the Pharma Segment irrespective of what Pharma Segment Business Area the project or product would be assigned to. While the Business Area contribution is reviewed on a monthly basis, as noted in our original response and above, the operating results for the Pharma Segment and Animal Health Segment are the main focus when making decisions related to resource allocation and assessing performance. As discussed further in our response below regarding the significance of the unallocated costs, in order for the CODM to evaluate and make decisions for the Pharma Segment, all of the information related to the Organizational Units and Pharma Segment Business Areas needs to be analyzed in total. This is why our CODM analyzes this information at the Pharma Segment level in order to allocate resources and make key operating decisions. For example, in 2015, we terminated the Phase III trial for evacetrapib which, if successful, would have been assigned to the Diabetes Business Area. As a result of the termination, we had extra R&D capacity in future years which allowed us to fund incremental R&D trials beyond those originally planned. The projects to which resources were allocated with the extra

R&D capacity all happened to be projects that if successful, would be assigned to Pharma Segment Business Areas other than the Diabetes Business Area. As discussed further below in our response to the Staff's question regarding the key factors that the CODM considers in making decisions on whether to advance R&D on a particular product, the Pharma Segment Business Area to which a particular project or product would be assigned is not a factor considered in making the resource allocation decisions to advance a particular R&D project. Also in making these decisions, our CODM is not using discrete financial information for any of the Pharma Segment Business Areas. Instead, our CODM prioritizes projects that are best for the Pharma Segment as a whole, regardless of the Pharma Segment Business Area.

The Pharma Segment Business Area contribution is included in the monthly and quarterly packages to provide data to our CODM on trends and how cost of sales and certain direct costs are moving in proportion to revenue. The Business Area contribution is not used to allocate resources between our Pharma Segment Business Areas as the key operational and resource allocation decisions for the Pharma Segment must also consider unallocated costs within the Pharma Segment of the Organizational Units (including R&D and manufacturing). Since these costs are so significant (annually ranging between approximately \$2.5 billion to \$3.0 billion), they impact the decisions made regarding our products, and conversely our product decisions significantly impact our R&D and manufacturing functions.

While the operating results (e.g., business area contribution) of these Pharma Segment Business Areas are regularly reviewed by our CODM, these results are used to supplement the operating results for the Pharma and Animal Health Segments, which are the main focus in helping make informed decisions when allocating resources between the operating segments and assessing performance. In situations where costs and/or revenues are outside of expectations, our CODM focuses on ensuring that the Pharma Segment as a whole can meet its profitability targets. If the overall Pharma Segment target is expected to be missed, our CODM will work with the Pharma Segment Business Area leaders and Organizational Unit leaders collectively to develop strategies to reduce costs within the segment in order to try and meet the established target for the Pharma Segment in total without regard to impacts to individual Pharma Segment Business Area results. Conversely, if the overall Pharma Segment target is expected to be exceeded, our CODM will work with the Pharma Segment Business Area leaders and Organizational Unit leaders collectively to identify areas for incremental investment or initiatives which could be pursued with the additional resources without regard to impacts to individual Pharma Segment Business Area results. The cost reduction or investment decisions are based upon what is best for the entire Pharma Segment and are pursued without any consideration for the respective Pharma Segment Business Area.

The focus on Pharma Segment results for performance assessment and key operational and resource allocation decisions is corroborated by the linkage of 100% of the Pharma Segment Business Area leaders pay-out of incentive compensation to consolidated results instead of the results of their Business Areas (please see our response below with respect to the Staff's question regarding incentive compensation) as well as the information that our CODM provides and presents to our Board of Directors (BOD) during the quarterly BOD financial reviews as discussed in our initial response.

As we have discussed, the key operating decisions made by our CODM related to the Pharma Segment including, most significantly, resource allocation decisions related to R&D and manufacturing, are on a compound-by-compound, indication-by-indication basis focused on what is best for the Pharma Segment as a whole and are not based upon the operating results of any of the Pharma Segment Business Areas. Therefore, we believe that this characteristic is not present for any of the Pharma Segment Business Areas.

c. Its discrete financial information is available.

Discrete financial information is available for each of the Pharma Segment Business Areas. This characteristic is present.

Other ASC 280 Considerations

As discussed in our previous response, as part of our analysis, we also considered ASC 280-10-50-6 which provides that if the CODM uses more than one set of segment information, "other factors may identify a single set of components as constituting a public entity's operating segments, including... information presented to the board of directors." We note that our conclusion that we are a two segment company is corroborated by the information that our CODM provides to our BOD. The information that is provided to the BOD, which does not include business area contribution for the Pharma Segment Business Areas but instead includes combined contribution information for the Pharma Segment, reflects the CODM's view of how the Company is performing and how the CODM is allocating resources when reviewing the overall performance of the consolidated Company and the two operating segments with the BOD. Our CODM does not use the contribution information for each of the four Pharma Segment Business Areas to assess business performance and allocate resources between the four Pharma Segment Business Areas.

Explain to us the business purpose for your organization structure that has four global Business Areas each having a senior VP whose performance is tied to an extent to the respective area's results and that provide discrete financial information relating to operating results regularly reviewed by the CODM. Address specifically why this organization structure and information regularly reviewed by the CODM does not inform the CODM's decisions in order to allocate resources to each of the four global Business areas and assess each area's performance.

Response:

Our segments are managed as separate operations with key operating decisions being made by the CODM based upon what is best for the Company as a whole, the Pharma Segment, and the Animal Health Segment. Our current organizational structure is based upon product groupings in strategic focus areas (with the exception of the Emerging Markets Global Business Area which was based upon geographic area) to ensure proper attention is given to both the short-term and long-term success of each product offering and to leverage the sales force across similar therapeutic areas in order to create efficiencies in the detailing of our product offerings. Because the nature of our business has such a long life cycle, requiring significant investments today to ensure new products a decade or more from now, we need to ensure that decisions are being made considering both the long-term success of the business as well as current profitability objectives. Our current organization structure is intended to accomplish this. From a short-term perspective, these four Pharma Segment Business Areas represent the selling and marketing functions for the Pharma Segment and are responsible for selling and marketing the drugs that successfully complete the R&D process. The CODM is not responsible for the decisions at the Pharma Segment Business Area level as these decisions are made by the Pharma Segment Business Area leaders, however, these decisions are not deemed to be the key operating decisions to allocate resources within the Pharma Segment. From a long-term perspective, as discussed further in our response below to the Staff's question regarding the factors considered for R&D decisions, the Pharma Segment Business Area leaders are responsible for providing input related to the therapeutic areas included in their Business Areas to the committee which makes significant R&D portfolio recommendations. Also as discussed further below, R&D portfolio decisions are made based upon what is best for the Pharma Segment as a whole.

We acknowledge that the financial information specifically reviewed by the CODM does include information at the Pharma Segment Business Area level; however, as mentioned in our response to your immediately preceding question above, the Pharma Segment results regularly reviewed by the CODM are the main focus and are used to make decisions about resource allocation and assess performance.

The key operating decisions made by the CODM related to the Pharma Segment, including significant resource allocation decisions related to R&D and manufacturing, are based upon what is best for the Pharma Segment as a whole and are not based upon nor informed by the discrete financial information of any of the Pharma Segment Business Areas. The Pharma Segment Business Area contribution is included in the monthly and quarterly packages to provide data to our CODM on trends and how cost of sales and certain direct costs are moving in proportion to revenue. As we have mentioned previously, our conclusion that the focus of key decisions for the Pharma Segment are based on what is best for the Pharma Segment overall is corroborated by the decision-making process for our key R&D and manufacturing investments, the linkage of the incentive compensation of the leaders of the Pharma Segment Business Areas to consolidated results instead of to the results of their Business Area, and the information presented to the BOD, which is how our CODM provides his overview and perspective of how the Company is performing.

- We note that key decisions around R&D, manufacturing, and the four global Business Areas within the Pharma segment are driven by the CODM who assesses the performance and determines the resource allocations of the entire pharmaceutical operations which are reported to the BOD. Please provide us with additional information to understand how these key operating decisions are made. Address the following:
 - Describe to us the key factors that the CODM considers in making decisions whether to advance R&D on a particular product and what specific information the CODM reviews in order to make these decisions.

Response:

When our CODM makes the major resource allocation decisions on whether or not to advance a particular product through the R&D process, the facts and circumstances surrounding each individual project or product are the key focus of these R&D resource allocation decisions. The Pharma Segment Business Area to which a particular project or product would be assigned is <u>not a factor</u> considered in making the resource allocation decisions to advance a particular R&D project. The role of the Pharma Segment Business Area leaders with respect to products under development is discussed further below.

The most significant factors that are considered and reviewed by both the committee making recommendations to our CODM and by our CODM regarding the resource allocation decisions on whether or not to advance R&D on a particular product include the following:

- the pTS;
- the unmet medical need and global market opportunities;
- the competitive landscape and external clinical data (i.e., could the project potentially be first-in-class or best-in-class);
- clinical trial results and clinical differentiation;
- strategic fit within targeted therapeutic areas;
- · manufacturing capabilities and required investments;
- scientific, regulatory, market, payer, legal, and financial risks for the project and how that compares to the rest of the Pharma Segment R&D portfolio; and
- a financial valuation with projected revenues and costs assuming successful development and commercialization of a molecule.

The committee, in making their recommendation, as well as our CODM, will review and consider documentation which includes each of the above factors in order to make the resource allocation decisions to advance a particular R&D project. The recommendation and decision is based upon the merits of the project, as well as the relative priority those merits give it across our portfolio, as our opportunities to invest in R&D projects generally outweigh our capacity to invest. Prioritization for R&D projects across the entire Pharma Segment is utilized to ensure the most impactful and valuable projects are progressed through development regardless of the Pharma Segment Business Area to which the project would be assigned.

• To the extent that the decisions involve any projections of potential future revenues and costs relating to those products, tell us who are responsible for determining those projections and how those projections are derived.

Response:

Projected financial information is one of many factors considered in the resource allocation decisions regarding which projects to advance through the R&D process. The financial valuation for an R&D project is primarily driven by the pTS and projected R&D expenditures, revenues, costs to manufacture the product, and operating expenses associated with the compound as if the compound were to successfully complete the R&D process.

One of the most important factors in our financial modeling is pTS, which increases as a product successfully moves through the R&D process. The pTS is estimated by a group within the Pharma Segment R&D organization, which is independent of all of the Pharma Segment Business Areas. The pTS takes several elements into consideration including but not limited to: the historical results of other compounds in development (by Lilly as well as the industry as a whole); how far along the compound is in development; whether or not the scientific hypothesis has been validated; and the unique aspects of the particular compound.

The anticipated R&D spend associated with completion of development of each compound is determined by the human pharmaceutical products R&D organization project management team and finance team, which are independent of all of the Pharma Segment Business Areas, and consider among other things: the indication being researched, historical internal and external data, such as disease state benchmarks, on advancing similar products through approval, anticipated size and length of required clinical trials, and the unique aspects of the particular compound.

Revenue projections for <u>all</u> potential pharmaceutical products are prepared by the market research group. While the market research group supports the entire Pharma Segment, it reports through the Bio-Medicines Business Area as this business area had the most revenue at the time our current organizational structure was established. The revenue projections take many factors into consideration including but not limited to: external market research; market growth estimates; the share of market that is able to be captured based upon the aspects of the compound under development; and the competitive landscape.

Cost of product sales projections and anticipated manufacturing investments are prepared by the human pharmaceutical products manufacturing organization strategy and finance teams, which are independent of all of the Pharma Segment Business Areas, and considers factors such as process, facility, and capacity requirements, historical data on manufacturing similar products, manufacturing strategy and anticipated future capacity, and the unique aspects of the particular compound.

Consistent with the structure of our Pharma Segment Business Areas, which represent the selling and marketing functions of our Pharma Segment, the forecasted operating expenses included in the projections are the only projections that are provided by the Pharma Segment Business Area finance groups and are based upon several factors including market size and demographics, historical operating expense data, and the competitive landscape. These projected operating expenses are generally not a significant driver to the financial projections as the majority of these expenses don't start for several years (not until the R&D process is completed and the product would receive regulatory approval) and they generally tend not to be as significant to the overall financial valuation of the project relative to the revenues and the significant development costs we incur for a number of years before any revenues are recognized.

• Explain the role of the individual business area leaders with respect to products under development.

Response:

The R&D portfolio resource allocation decisions are evaluated by a committee which is chaired by the EVP of Science and Technology and our Chief Financial Officer, and includes the Pharma Segment Business Area leaders. As discussed in our response above with respect to the Staff's question regarding the factors and information reviewed in making R&D resource allocation decisions, there are several pieces of important information that are considered in making these evaluations. The Pharma Segment Business Area leaders compile this information from the various sources we discussed previously and are responsible for presenting the information to the committee for compounds which would be expected to be assigned to their respective Pharma Segment Business Area's product portfolio if the compound were successful. In addition to presenting information, the Pharma Segment Business Area leaders also participate along with the committee chairs in the evaluation of compounds presented by the other Pharma Segment Business Area leaders for compounds that would be assigned to their Business Area (e.g., the leader of the Diabetes Business Area would listen to presentations made by the other Pharma Segment Business Area leaders and would assist in the evaluation of those compounds). While the Pharma Segment Business Area leaders present the information for compounds that would be assigned to their Business Area, because the focus is on the Pharma Segment as a whole, they will not recommend that these compounds be advanced if they believe there are more compelling opportunities with other compounds. It should also be noted that they do not have the unilateral decision-making authority to terminate an R&D project. The chairs of the committee review all of the information from the Pharma Segment Business Areas and Organizational Units collectively and make a recommendation to our CODM. As previously mentioned, our CODM is responsible for decision making relative to R&D resource allocation decisions and whether or not to move programs into the next stage of development.

• With respect to manufacturing, it appears that products across all of your Pharma Business Areas are produced at shared facilities. Tell us who are responsible for allocating production capacity for different products and how that individual interacts with the business area leaders in making those decisions.

Response:

Capacity decisions as well as other key manufacturing decisions including investments in manufacturing facilities and sourcing decisions are driven by the human pharmaceutical products manufacturing organizational unit. The key manufacturing decisions are decided by our CODM after taking into consideration the recommendations by the Manufacturing Policy Committee which is chaired by the President of Manufacturing Operations (the leader of the human pharmaceutical products manufacturing organization, who reports directly to our CODM). This committee is comprised of individuals who report directly to the President of Manufacturing Operations, as well as representatives from quality and information technology (Global Services), who each report to the leaders of their respective Organizational Units. The Manufacturing Policy Committee meets on a routine basis to internally discuss any outstanding sourcing and capacity decisions. Representatives from this committee also meet periodically with the Pharma Segment Business Area leaders to discuss the long-term plan, sales and demand forecasts, as well as the expected timing of launches for pipeline products (as provided by the human pharmaceutical products R&D organization). The inputs from these discussions are considered by the Manufacturing Policy Committee in developing their recommendations to our CODM, however, the chair of the committee ultimately decides what is presented and recommended to the CODM, who is responsible for these decisions.

• We note from your response that unexpected variances resulting from issues experienced at a manufacturing facility would not be allocated to the business areas. Please tell us whether and, if so, to what extent your other manufacturing costs are allocated to each of your Pharma Business Areas.

Response:

As the Pharma Segment Business Areas represent the selling and marketing functions of the Pharma Segment, they are not held accountable for any manufacturing decisions or manufacturing performance throughout the year because the Pharma Segment Business Areas do not control manufacturing decisions or operations. This is demonstrated by the manufacturing costs which are allocated to the Pharma Segment Business Areas which include the standard unit costs, royalties from licensing arrangements, planned manufacturing variances, and distribution costs. The planned manufacturing variances that are allocated to the Pharma Segment Business Areas are set during the annual budgeting process when the upcoming year's total expected manufacturing variances for the Pharma Segment are calculated. The portion of the planned manufacturing variances that is allocated to the Pharma Segment Business Areas is based upon the forecasted production volumes for the Pharma Segment Business Areas and mainly includes planned variances related to idle plant costs. Any unexpected variances and the financial impact of manufacturing decisions made throughout the year are not allocated to the Pharma Segment Business Areas and the Pharma Segment Business Areas are not held accountable for these unplanned variances and manufacturing decisions.

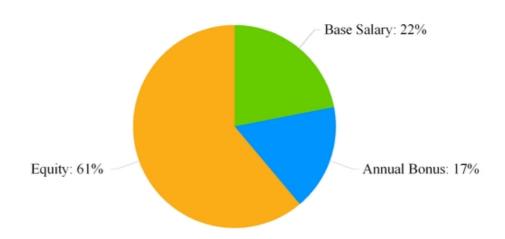
- We note that approximately 70% of the incentive compensation for Pharma Business Area leaders is based on consolidated results. In addition, we note that awards for executive officers may relate to their specific area.
 - Clarify what is meant by your statement the fact that all of the CODM's direct reports have their compensation tied to the results of the entire company rather than their Pharma Segment Business Area or Organizational Unit supports the conclusion that human pharmaceutical products is one operating segment.
 - Clarify what portion, if any, of the business leaders' incentive compensation is based on his/her respective business area's results, and also what portion, if any, is based on the results of the Pharma segment. Tell us how you considered this incremental incentive compensation in your analysis as to whether each of your Pharma Business Areas is an operating segment.

Response:

Our response that follows first responds to the comment in the second sub-bullet as it provides context to our response to the comment in the first sub-bullet.

We would like to respectfully clarify the Staff's understanding of the Pharma Segment Business Area leaders' total pay. We noted in our initial response that 70% or more of each executive officers' target total pay is incentive compensation (equity and annual bonus) which is entirely based upon the consolidated results of the Company. The remaining piece of target total pay (beyond incentive compensation) is base salary. The chart below represents the average mix of target total compensation for the four Pharma Segment Business Area leaders for whom these incentive programs deliver 78% of target total pay.

Pharma Segment Business Area Leader Target Total Compensation Mix (Average)



We note that the portion of the Pharma Segment Business Area leaders target total pay to be earned related to incentive compensation (equity and annual bonus) is <u>entirely</u> based upon the consolidated results of the Company. Annual base salary adjustments can be influenced by the results of their respective Pharma Segment Business Area; however, the Pharma Segment Business Area performance is only one of many factors considered during the annual review of base salary. Other factors taken into consideration during the annual review of base salary include the level of responsibility and expertise of the individual as well as peer group data. We also note that there is no formula for determining the annual base salary adjustment and, as a consequence, the portion of any base salary adjustment tied to the performance of the Pharma Segment Business Area is not objectively defined or determinable. The base salary adjustments for our Pharma Segment Business Area leaders averaged approximately 3% in 2015 and have historically represented an insignificant percentage of the Pharma Segment Business Area leaders' total compensation. It is also relevant to note that every employee's base salary adjustment is based upon their accomplishments for the year relative to their objectives.

We believe the structure of the Pharma Segment Business Area leaders' compensation package supports our conclusion that our human pharmaceutical products business is one segment as only an insignificant portion of the Pharma Segment Business Area leaders' total compensation package can be influenced by their respective Pharma Segment Business Area's results, which provides evidence that performance is not being assessed at the Pharma Segment Business Area level.

Regarding our statement that the linkage of the compensation of the CODM's direct reports to the results of the entire company as support for our conclusion that the human pharmaceutical products is one operating segment, we thought it would be informative to consider the structure of the incentive compensation of the Pharma Segment Business Area leaders in evaluating whether or not the Business Areas meet the criteria of an operating segment, as the structure of the incentive compensation is an indication of how the CODM assesses performance. For example, if the payout of incentive compensation for the Pharma Segment Business Area leaders was tied to the results of their respective Business Area, this could be an indication that the Business Areas represent separate operating segments. However, since payouts of the incentive compensation awards of our Pharma Segment Business Area leaders are determined by consolidated results only, we believe that this as an indication that the Pharma Segment Business Areas do not represent separate operating segments. Further, as we noted on page 10 of our original response, since we are primarily a human pharmaceutical products company, we believe tying executive pay to performance of the consolidated Company for the Pharma Segment Business Area leaders is a proxy for the performance of the Pharma Segment. We believe this linkage supports the conclusion that human pharmaceutical products is one operating segment.

As additional background to support our statement that we are primarily a human pharmaceutical products company, we note that:

- Our Animal Health Segment was not large enough to require separate disclosure until 2014; and
- In 2015, our Pharma Segment revenues were 84 percent of consolidated revenue and our Pharma Segment profits were 87 percent of total segment profits.

3. Please refer to your response to prior comment 3. Tell us more specifically where the impacts that you discuss have been appropriately addressed in your filing. Provide us your analysis in determining the extent to which your MD&A should also include a discussion on a segment basis. Refer to Part III F.1. Segment Analysis in our May 1989 MD&A interpretive release.

Response:

For ease of reference, here was our response to your first letter:

"Human pharmaceutical products

Foreign exchange rates had an unfavorable effect on our human pharmaceutical product revenues and a favorable impact on costs of product sold and operating expenses. Excluding the impact of foreign exchange rates, our human pharmaceutical product revenues would have increased 5 percent, and our human pharmaceutical products segment profit would have increased 12 percent, compared to 2014. Reductions in our marketing, selling, and administrative expenses, primarily resulting from the Cymbalta® and Evista® patent losses, held operating expenses relatively flat, which along with the effect of foreign exchange rates, drove the increase in segment profit compared to revenue.

Animal health

The increase in animal health revenues is due to the inclusion of sales from Novartis Animal Health (Novartis AH) of approximately \$1.0 billion, which we acquired on January 1, 2015 (Note 3), and were partially offset by the unfavorable impact of foreign exchange rates.

The flatness in segment profit was driven by higher marketing, selling, and administrative expenses, as rationalization efforts related to the integration of Novartis AH were not yet fully-realized in 2015.

We believe these impacts have been appropriately addressed in our 10-K filing."

In response to your inquiry regarding where the impacts that we discuss have been appropriately addressed in our filing:

The following is a summary of the impacts discussed in our first response and the corresponding disclosures in our filing. Certain text has been underlined in our response for emphasis.

Human pharmaceutical products

Impact discussed in our first response:

"Foreign exchange rates had an unfavorable effect on our human pharmaceutical product revenues and a favorable impact on costs of product sold and operating expenses."

Relevant disclosures:

- MD&A Operating Results 2015 Revenue (page 39): We provide a table that quantifies the unfavorable impact of foreign exchange rates on global revenue.
- MD&A Operating Results 2015 Revenue (pages 40-41): We disclose the unfavorable impact of foreign exchange rates as a driver for specific pharma product explanations, including Humalog®, Alimta®, Cialis®, Forteo®, Humulin®, Cymbalta, Zyprexa®, Strattera®, Effient®, and Evista.
- MD&A Operating Results 2015 Gross Margin, Costs, and Expenses (page 41),

"Gross margin as a percent of total revenue was 74.8 percent in 2015, essentially flat compared with 2014 as the unfavorable impacts of Novartis AH and inventory step-up and amortization costs were offset by the <u>favorable impact of</u> foreign exchange rates on international inventories sold."

• MD&A - Operating Results - 2015 - Gross Margin, Costs, and Expenses (page 41),

"Research and development expenses increased 1 percent to \$4.80 billion in 2015, driven primarily by higher late-stage clinical development costs, the inclusion of Novartis AH, and an increase in charges associated with the termination of late-stage molecules, primarily Evacetrapib and basal insulin peglispro, of approximately \$135 million, partially offset by the favorable impact of foreign exchange rates."

MD&A - Operating Results - 2015 - Gross Margin, Costs, and Expenses (page 42),

"Marketing, selling, and administrative expenses decreased 1 percent to \$6.53 billion in 2015, due to <u>the favorable</u> <u>impact of foreign exchange rates</u> and a 2014 charge associated with the U.S. Drug Fee, partially offset by the inclusion of Novartis AH and expenses related to new product launches."

Impact discussed in our first response:

"Reductions in our marketing, selling, and administrative expenses, primarily resulting from the Cymbalta and Evista patent losses, held operating expenses relatively flat, which along with the effect of foreign exchange rates, drove the increase in segment profit compared to revenue."

Relevant disclosures:

While we did not specifically discuss the Cymbalta and Evista patent losses as a driver for keeping operating expenses flat, our explanation on page 42 for marketing, selling, and administrative expenses (shown above) cites the 2014 charge associated with the U.S. Drug Fee as a driver for the lower expense in 2015. The Cymbalta and Evista patent losses were a significant driver for the lower U.S. Drug Fee in 2015 compared to 2014.

Animal health

Impact discussed in our first response:

"The increase in animal health revenues is due to the inclusion of sales from Novartis Animal Health (Novartis AH) of approximately \$1.0 billion, which we acquired on January 1, 2015 (Note 3), and were partially offset by the unfavorable impact of foreign exchange rates."

Relevant disclosures:

• MD&A - Other Matters - Novartis Animal Health Acquisition (page 36),

"On January 1, 2015, we completed our acquisition of Novartis AH in an all-cash transaction for \$5.28 billion."

MD&A - Operating Results - 2015 - Revenue (page 41),

"Revenues of animal health products in the U.S. increased 21 percent and animal health product revenues outside the U.S. increased 53 percent. The increases were driven by the inclusion of revenue from Novartis AH.

On a proforma basis, which reflects the 2014 revenues of Novartis AH as described in Note 3 to the consolidated financial statements, revenues of animal health products in the U.S. would have decreased 1 percent, driven primarily by decreased volume in food animal products. Revenues outside the U.S. would have decreased 13 percent, driven by the unfavorable impact of foreign exchange rates and decreased volume in companion animal products, partially offset by higher realized prices and volume for food animal products."

• Note 3 (page 63),

"Our consolidated statement of operations for the year ended December 31, 2015 includes Novartis AH revenue of \$1.02 billion."

• Note 18 (page 101),

"The animal health segment amounts for the year ended December 31, 2015 include the results of operations from Novartis AH, which was acquired on January 1, 2015 (Note 3)."

Impact discussed in our first response:

"The flatness in segment profit was driven by higher marketing, selling, and administrative expenses, as rationalization efforts related to the integration of Novartis AH were not yet fully-realized in 2015."

Relevant disclosures:

• MD&A - Operating Results - 2015 - Gross Margin, Costs, and Expenses (page 42),

"Marketing, selling, and administrative expenses decreased 1 percent to \$6.53 billion in 2015, due to the favorable impact of foreign exchange rates and a 2014 charge associated with the U.S. Drug Fee, partially offset by the inclusion of Novartis AH and expenses related to new product launches."

• Note 3 (page 63),

"The goodwill recognized from this acquisition is attributable primarily to <u>expected synergies that we believe will result</u> from combining the operations of Novartis AH with our <u>legacy animal health business</u>, future unidentified projects and products, and the assembled workforce of Novartis AH."

"Novartis AH has been partially integrated into our animal health segment and as a result of these integration efforts, certain parts of the animal health business are operating on a combined basis, and we cannot distinguish the operations between Novartis AH and our legacy animal health business."

In response to your inquiry regarding our analysis in determining the extent to which our MD&A should also include a discussion on a segment basis:

Part III F.1. Segment Analysis in the SEC's May 1989 MD&A interpretive release states,

"In formulating a judgment as to whether a discussion of segment information is necessary to an understanding of the business, a multi-segment registrant preparing a full fiscal year MD&A should analyze revenues, profitability, and the cash needs of its significant industry segments. To the extent any segment contributes in a materially disproportionate way to those items, or where discussion on a consolidated basis would present an incomplete and misleading picture of the enterprise, segment discussion should be included."

We believe the Pharma and Animal Health Segments do not contribute to revenues, profitability, or cash needs in materially disproportionate ways. For example,

- The Pharma Segment's revenues and profit as a percent of total segment revenues and profit were 84% and 87%, respectively, in 2015 compared to 88% and 85%, respectively, in 2014.
- The Animal Health Segment's revenues and profit as a percent of total segment revenues and profit were 16% and 13%, respectively, in 2015 compared to 12% and 15%, respectively, in 2014.

We believe the above percentages indicate that each segment's revenues and profit are materially proportional to one another in the context of our consolidated results. Furthermore, there is no significant proportional difference in the cash needs of the two segments on an ongoing basis (excluding acquisition purchase prices which are special situations and such cash uses are specifically disclosed in our filings).

We believe discussing our operating results on a consolidated basis does not present an incomplete or misleading picture of our company. Our MD&A disclosures discuss the significant drivers of the Animal

Health Segment, including the impact of the acquisition of Novartis AH, on both our animal health revenue and consolidated results of operations.

While Animal Health Segment profit declined despite an increase in segment revenue, we disclose in Note 3, "*Novartis AH has been partially integrated into our animal health segment*". We further disclose in Note 3 that we expect synergies will result from combining the operations of Novartis AH with our legacy animal health business. We believe these disclosures provide users with adequate information regarding the comparatively low segment profit of the Animal Health Segment when compared to segment revenue growth in 2015. To further assist with analysis of the Novartis AH acquisition's impact on revenues and profitability, we provide unaudited pro forma consolidated results in Note 3 (and related pro forma revenue for the Animal Health Segment on page 41 of our MD&A) as if Novartis AH were acquired on January 1, 2014.

In summary, we believe our discussion of consolidated results have addressed the significant drivers of the Pharma and Animal Health Segments; therefore, discussion on a consolidated basis is not misleading.

We acknowledge that:

- we are responsible for the adequacy and accuracy of the disclosure in the 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
- we 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 317-651-2310.

Sincerely,

ELI LILLY AND COMPANY

Donald A. Zakrowski Vice President, Finance and Chief Accounting Officer