Divis Laboratories Ltd.

“Divi’s Laboratories Ltd. Conference Call”

March 27, 2017

Divis Laboratories Ltd.

MANAGEMENT: **DR. MURALI K. DIVI – CHAIRMAN AND MANAGING DIRECTOR**
MR. N. V. RAMANA – EXECUTIVE DIRECTOR
MR. KIRAN DIVI – DIRECTOR
MR. KISHORE BABU – CHIEF FINANCIAL OFFICER

Moderator: Ladies and Gentlemen, Good Day and Welcome to the Divi's Lab Conference Call. As a reminder, all participant lines will be in a listen-only mode. And there will be an opportunity for you to ask questions after the presentation concludes. Should you need assistance during the conference call, please signal for an operator by pressing "*" followed-by "0" on your touchtone phone. Please note that this conference is being recorded. I now hand the conference over to Mr. Kishore Babu – CFO of Divi's Labs. Thank you and over to you, sir.

Kishore Babu: Thank you very much. Hello, everybody. I am Kishore Babu, CFO of the company. And thank you all for joining us today on this conference call. I am sure, by now you are all aware of the Form 483 observations of US-FDA for the recent inspection of our unit and the subsequent Import Alert issued by FDA.

On this con-call, we have with us our Management team comprising Dr. Murali K. Divi – Chairman and Managing Director, Mr. N. V. Ramana – Executive Director and Mr. Kiran Divi – Director to address queries of analysts and investors, relating to the US FDA inspection.

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Ladies and Gentlemen, we will wait for moment while the questions are assembled. Meanwhile, I would request Dr. Divi to give an introduction.

Murali K. Divi: Good morning. I am Murali Divi, Chairman and Managing Director of Divi's Laboratories. Thank you all for joining us for this con-call.

As you are aware, that we have had an inspection from US FDA in December 2016 and FDA had issued a Form 483 with five observations. And have subsequently received an Import Alert last week.

I wish to share with you, our understanding of the events and the way forward for resolution. You are aware we have filed our detailed response to the observations within the stipulated time. (We have also started remediation of deficiencies. We also filed the CAPA (Corrective And Preventive Action) in our detailed response to the five observations and we have committed to further file additional information by January 31st and there will be one more submission by March 31st. The January filing has since been done and March filing will happen this week.

The import alert came as a surprise. To our understanding, usually import alert is issued after a warning letter and if issues or concerns that are raised were not addressed to the satisfaction of the FDA. We have to await for the communication from US-FDA on our 483 response and remediation plan. In the import alert, FDA has given exemption for a majority of our products based on their own evaluation of shortage of drugs. We and our customers will also be approaching FDA for exemption of few more products, both in custom synthesis and also in generic segments.

We have engaged reputed consultants and subject matter experts for advising us on 483 responses and the remediation efforts in order to overcome the deficiencies and fully comply with the cGMP (current Good Manufacturing Practices) requirements.

Divi's have had five inspections for Unit-1 and six inspections for Unit-2 by FDA. And all these inspections were successful with minor or nil observations. Divi's always gave utmost importance to compliance to full cGMP and meeting all the requirements of the US-FDA.

With this, I would request you to field your queries. Thank you.

Moderator: Thank you, sir. Ladies and Gentlemen, we will now begin with the question-and-answer session. Our first question is from the line of Amey Chalke from HDFC Securities.

Amey Chalke: My first question is regarding top-line exposure to US market from Unit-2. I believe we have received some statement from some place that only 5% of our top-line is affected due to this import alert. Is it right assessment?

Kishore Babu: It is right. As you know that exports constitute about 60% - 65% from the Unit-2, and exports to North America is about 32%. And including indirect supplies to US market from other regions by the formulators, our overall exposure to the US market from Unit-2 would be approximately about 22% - 23%. Import alert as you know has exempted 10 products, hence we estimate that less than about 5% of our business may be impacted due to import alert.

Amey Chalke: And obviously, we must have appointed a consultant for this remediation, so going ahead there would be batch by batch processing. Or if that is happening, then how would be the incremental impact because of the slow supply chain basically after this import alert?

N.V.Ramana: This particular import alert and the exemptions and how to operate, a methodology has been given to us and we will be following the procedure provided by FDA. We are right now working with the consultants and customers on setting up the procedure and these modalities will be put into operation very soon and we will be working through that modality.

Amey Chalke: And second question is related to exposure to Europe basically, from these two units, if you can provide that visibility.

N.V.Ramana: Please repeat your question.

Amey Chalke: Exposure to Europe market for API generic from Unit-1 and Unit-2.

Kishore Babu: You know the business distribution, we have already mentioned that approximately about 40% is the exposure to the European market and the same thing remains.

Amey Chalke: And any reason if you can highlight why the two inspections, first inspection happened in February 2016 and second happened in December 2016, why there was a little gap between two inspections, any reason for this re-inspection so quickly by the US FDA, if you can highlight?

N. V. Ramana: See, right now what we know is the inspection in early 2016 was a prior approval inspection for a specific product. Then, this is a general cGMP inspection for the periodic inspection. So this is what we know from what we have been given as the field people's mandate.

Amey Chalke: Now we have received the import alert for this facility, so any plans to fast track our Kakinada facility or any other new facility going ahead?

Kishore Babu: Well, that would take its own course. The priority for us is to be able to overcome the deficiencies and put the remediation plan immediately. And beyond that, there could be separate plans for other expansions which can go paralelly.

Moderator: Thank you. Our next question is from the line of Surya Patra from PhillipCapital. Please go ahead.

Surya Patra: Sir, we have got the import alert directly and before the warning letter itself. So, is it going to impact our remediation process? And if whatever the remediation activities that we are currently doing, so are we aware that what all needs to be done?

Murali K. Divi: The import alert, this came as a surprise to us and we are ascertaining the possible reasons for this. We have already taken up the necessary measures to address the concerns of US FDA and are putting in earnest efforts to fully meet this cGMP compliance requirements. And this has been addressed in the CAPA submitted to US FDA.

Surya Patra: But, in whatever communication that so far we have received from the FDA side, whether there is any clarity about what all remediation activities need to be done, sir?

N. V. Ramana: See, in the 483 response which we have already submitted, we have given our explanations to the observations and subsequent to that we have this import alert. We do not have a response from FDA on how they have evaluated; and we are waiting for the communication to come from FDA.

Surya Patra: So that means we would be even waiting for the warning letter also, right?

N. V. Ramana: We cannot anticipate those things. But as I said, first our response needs to be evaluated or they have evaluated, we await that communication. So we will wait for the communication from FDA.

Surya Patra: And one more thing, in the opening remarks you have mentioned that Divi's as well as customers of Divi's are requesting for exemption of more products. So, can you just give some more clarity about it?

Murali K. Divi: In addition to the products where already they were mentioned in the import alert, these products….., it appears FDA has evaluated on their own and gave exemptions in the list mentioned in the IA. Yes, you are right that we and our customers will also be approaching FDA for exemption of few more products both in custom synthesis and also in generic segment.

Surya Patra: Okay. But any idea about it sir, in what way or those are like very important so that is why they should give exemption, some idea about the new product that we are trying for exemption?

Murali K. Divi: I think when it comes to the generic industry, these are not the new products, these are the products we have been supplying to the US. But as Kishore Babu mentioned, the impact is about 5% in the range. So, you are not looking at the big products, I think the larger products of Divi's Labs have been exempted. So, we are looking at customer-based requirements, in other words, our generic industry customers who have some specific products which may cause some anxiety in the shortage of ..…, I think that is how the request will be made. The same thing with our custom synthesis customers where either some of the intermediates or APIs, I think they will be requesting the FDA.

Surya Patra: So, net, net sir, it indicates that since anyway our revenue impact out of this exemption is limited only, 5% that what you have been saying. And if more products would be exempted, then the real revenue impact would be negligible only?

Murali K. Divi: I would say it will be less than whatever Kishore Babu mentioned, 5% based on the number of exemptions that will be given.

Surya Patra: Sir, can you just talk on the export methodologies what you have mentioned, or what that you have received from the US FDA. So, whether it is requiring a batch by batch verification by third party or any third party has already been identified by US FDA, any clarity on this?

N.V.Ramana: As already explained, they have given us a methodology in which the verification has to be done by a third party, we are discussing with third party. And, we will be putting this procedure in place.

Moderator: Thank you. Our next question is from the line of Mayank Hyanki from Axis Mutual Fund.

Mayank Hyanki: I would like to understand your assessment of the import alert, the main reasons for that? And do you see that your initial take on the matter that the lab area was not under purview of the GMP, is that one of the main problems why the import letter has come up? And secondly also, we have also been hearing on talks of whistleblower being there in this, if we can clarify on that also whether you think that this inspection was triggered by a whistleblower act or it was a normal inspection?

Kiran Divi: To answer this question, this import alert came to us as a surprise and we are also equally ascertaining the possible reasons of why we got the import alert. We cannot attribute any single condition on why Divi's has received the import alert. All we can say is we need more clarity; and we will have better clarity once we hear from FDA after they review our response.

Mayank Hyanki: Okay. Secondly, on the impact part, we wanted to know that will this also impact any approvals pending from the partner site or has it already been shown in the last two, three months, plus also on the new orders front in terms of on the API front or on the custom synthesis part. So, have you felt, seen anything in the last three, four months?

Kiran Divi: It is yes and no; new products could be approved from Unit-2 as long as there is some kind of urgency which is visualized by FDA or from our customers assisting them.

Mayank Hyanki: And on the custom synthesis part?

Kiran Divi: Like Dr. Divi has mentioned, our customers and ourselves are approaching FDA, and to drug shortage…., expressing if there would be any concerns in the supplies**.**

Mayank Hyanki: And what are you hearing, what are you communicating to the clients right now, and more importantly what is the communication from their end, in terms of the current supply?

Murali Divi: We are personally discussing the issues with majority of our customers, in generic as well as custom synthesis segment and are keeping them appraised of our remediation efforts.

Mayank Hyanki: And on their response part?

N. V. Ramana: So, as you know customers are actually familiar with the FDA procedures. So, we have been keeping them appraised and right now they are satisfied with the way we are working on the remediation.

Moderator: Thank you. Our next question is from the line of Nitin Gosar from Invesco Mutual Funds.

Nitin Gosar: I just wanted to understand your detailed analysis of data integrity issue, especially the clause 99-32 which was been invoked in your case. And what are the measures or what are the remedial plans to ensure that this kind of episodes do not occur in future?

N.V. Ramana: As you know, this import alert with the clauses has just come in. We have been discussing with our consultants on what could be the reason based on our 483 and subsequent response. Since we did not get any further communication from FDA, at this time, we can only try to guess, but we will not know exactly what could be the reason.

Nitin Gosar: So would it be right to understand the initial response which would have gone from your side, would not have taken into account the observations like 99-32 which they have come up with, would that be a fair understanding?

N.V. Ramana: Again, like I said, at this point it is difficult for me to answer this, on what the FDA is thinking or why they have given an import alert without communication to us.

Nitin Gosar: And sir, the products where we have got exempted, are we the single source supplier or are we like dual source or may be, one of the multiple source suppliers to those customers?

N. V. Ramana: See, the list of exemptions is based on FDA's evaluation by the drug shortage office. And our customers and we are……., we could be the dominant supplier or there could be multiple suppliers, but it leads to a shortage….. is the assessment, that is why they have been put under exemption. This is our understanding.

Nitin Gosar: And the batch by batch clearances, it entails lot of additional cost, can we get some bit of clarity on the additional cost that you will have to incur on day to day basis for clearing those batches?

N. V. Ramana: I think this is quite early to estimate cost, there will be additional cost for sure, but it is difficult to estimate and give a number.

Nitin Gosar: And it will be great, hereon, in future communications, if you can bifurcate the additional cost and remediation part and the one which is required by batch-by-batch clearing part.

N. V. Ramana: Sure.

Moderator: Thank you. Our next question is from the line of Cyndrella Carvalho from Dolat Capital.

Cyndrella Carvalho: Sir, my question pertains to…. based on the five observations that we have, what are the key milestones that we should look for in terms of resolution? Like we are aware about something that we have been talking like meeting with US FDA, what are the other key milestones that we should look forward to?

N. V. Ramana: See, there is a set procedure by which we have to go with the process of remediation. So, the 483 responses have been submitted in time, like our Chairman said in the opening remarks. Then we agreed to give them a first update in January, which we have done, and there is another update which is due and we will be sending in this week. Then we have to await, after their evaluation when they get back to us… that is the process.

Cyndrella Carvalho: Okay, so we will be waiting for further communication. And sir, any idea in terms of getting a meeting with the US FDA, would that help us anywhere?

N. V. Ramana: See, as I said, first we need to wait for their responses, and in the meanwhile we will be working towards what else we should do in remediation, we are talking to the consultants. And based on standard procedures what can be possible, we will try.

Cyndrella Carvalho: And sir, no further clarification that we have on the 99-32 right, as of now?

N. V. Ramana: As I said, this is early, we only have the intimation, so we will have to see what are the causes behind it and so on, as we go forward.

Moderator: Thank you. Our next question is from the line of Kumar Saurabh from Motilal Oswal Securities.

Kumar Saurabh: Sir, if you can help us understand, so this 5% calculation, this is purely on the basis of exempted list, as in 22% you are saying was the exposure, so does it mean that the exempted list account for 17% or we are also factoring in shifting of some business to Unit-1?

Kishore Babu: No, we did not factor shifting part of it. What we factored is the indirect exports through our formulators as well to the US market and all that is factored into……, and hence we see about 5% could be the impact of the products which are not exempt.

Kumar Saurabh: When you say indirect supply, what do you mean by that?

Kishore Babu: We supply to other markets and they would formulate and sell to the US market.

Kumar Saurabh: And sir, I know this is quite early, but with our interactions with the consultants, do we have a timeline in mind, by when do we think that we will be able to take the remediation action?

Kiran Divi: Like Dr. Divi has already explained, we have already taken the remediation action on the 483 given to us. We are still awaiting from the FDA on what further actions we have to take, and it is too early for us to assume anything.

Kumar Saurabh: And sir, as one of the previous person asked the question, is there a risk that, in European exposure also, there is a risk of loss of business, because any client may see this as a concern and may pull out business.

N. V. Ramana: See, the thing is European regulations are different. And Europe approvals also are available with us, there was no issue with the European approval earlier. But what actions customers will take as a risk mitigation or a business continuity, at this time we do not have any expression from customers of that nature.

Kumar Saurabh: And sir, Unit-1, how should we look at the growth for FY18 and FY19, revenues for FY18 and FY19 for Divi's? Our understanding was that Unit-1 was already running at 95% capacity utilization and Kakinada facility may still take some time to come back for commercialization. So, how should we look at FY18 and FY19 in terms of revenue and EBITDA?

Kishore Babu: We have been saying that we are operating at about 87% capacity utilization, and of course this has come in now. We have been broadly saying that this Kakinada is getting delayed because of the issues with the Government and hence we are gearing additional capacities at the existing sites. Now, we have also been broadly guiding that in the next couple of years we could be growing at about 10%. And now we know what products are impacted, and hence to that extent the 5% impact would be there in the existing business. And we have spent almost about Rs. 400 crores this financial year across Unit-1 and Unit-2 for augmenting capacities. For FY18, we have taken an expansion project at Unit-1 for creating additional two production blocks at an estimated cost of about Rs. 175 crores. We are also trying to spend an amount of Rs. 25 crores in FY18 for upgradation towards increase of capacity at Unit-2.

Kumar Saurabh: Sir, how much cash do we have in our books currently, is there a possibility of one-time dividend or a buyback?

Kishore Babu: We have cash of almost about Rs. 1,700 crores.

Kumar Saurabh: And can we do a buyback or, you know, our share price has corrected quite a bit, right, so…?

Murali Divi: I think at this point our prime goal is to get into full cGMP compliance as early as possible. And we agree that this is an unprecedented situation, we are concerned about the value erosion and

shall be making earnest efforts towards remediation and to fully meet the cGMP compliance requirement. So, we cannot comment at this stage on buyback, but this is an option.

Moderator: Thank you. Our next question is from the line of Bino Pathiparampil from SBI Cap Securities.

Bino Pathiparampil: Mr. Kishore Babu, I could not clearly understand how you calculated this 5%. To begin with, may I know how much Unit-2 contributes to your top-line?

Kishore Babu: Unit-2 contributes approximately 60% to 65% of sales.

Bino Pathiparampil: And of that 32% is to North America?

Kishore Babu: Right.

Bino Pathiparampil: 32% of 65% from Unit-2?

Kishore Babu: Right.

Bino Pathiparampil: And then, you said there are some products which you give to third party formulators who sell into US, is that included in this 32%?

Kishore Babu: No, that is why I said direct and indirect exports from Unit-2 could be in the region of about 22% to 23%.

Bino Pathiparampil: So, 22% to 23% of Unit-2 sales or overall company sales?

Kishore Babu: Total sales.

Bino Pathiparampil: Which actually does not add up because 32% of 65% itself comes to 20%.

Kishore Babu: Yes, another 3%; that is what I said.

Bino Pathiparampil: So that is 22%. So of this 22% of total sales, you are saying about 17% could be these exempted products?

Kishore Babu: Yes.

Bino Pathiparampil: And my understanding is also that these products which you give to third party formulators, if you have an import alert on your facility they would not be able to further export it to the US.

Kishore Babu: Are they not part of the exempted list?

Bino Pathiparampil: And finally, Dr. Divi, I would like to hear some comments about what went wrong this time around, was there some issue with the oversight capabilities that you have had all these years that something deteriorated in your plans or is it just that FDA tightened their requirements this time around?

Murali K. Divi: Of course, when you look at all the inspections that were going around in the last one to two years, I think our experience of the inspections in the last 15 years and the recent inspection, I think this came as a surprise to us and we are ascertaining the possible reasons for this on the 483. That is why we are spending considerable time on this, not only ourselves and other experts, we involved few US consultants, and not only consultants, but also the subject matter experts in each of the area, **t**he experts of the world. We are utilizing them to see what exactly is the remedial action we should be implementing to reach the expectations of the US FDA.

Bino Pathiparampil: One last quick question, in general do your customers in the US have alternate suppliers pre-approved or would you be generally the sole supplier for them, in general?

N. V. Ramana: I think we have already answered this question, there are some products where we could be the sole supplier or dominant supplier, and there are the others where they are dual sourced.

Moderator: Thank you. Our next question is from the line of Aditya Khemka from DSP Blackrock.

Aditya Khemka: So, Dr. Divi, if you could help us understand the exposure to Canada, I mean, is Canada a meaningful component of our overall sales?

Murali K. Divi: The Canadian Health Authorities have asked us for additional information pertaining to the Form 483 issued by the US FDA. And we have filed the required information with Canadian Health on the lines of the response filed with the US FDA.

Aditya Khemka: Right. But what percentage of our total sales will be coming from the Canadian geography?

Murali K. Divi: It is very less, compared to the US market.

Aditya Khemka: And in terms of Europe, as Kishore Babu was saying that about 22% - 23% is the end sales to US. Could we also quantify our end sales to UK and Europe, could you break it that for us?

Kishore Babu: Well, all Europe put together, we have disclosed, and it is about 40 odd%. It is there in the business distribution segment.

Aditya Khemka: And how much of that could be UK, Kishore Babu, do we have a clue on that?

Kishore Babu: We do not have a number for it right now, we have not made disclosure on that.

Aditya Khemka: And just to understand this a little better, so we read some newspaper articles in August 2016 which indicated that there was a refusal of inspection of Divis Pharma facility which I think is a private entity and not really Divi's Labs. You think the 99-32 classification is linked to FDA misinterpreting that as in … taking the Divis Pharma refusal of inspection and reading it across to Divi's Lab, I mean, do you think that is a possibility?

Kishore Babu: It is very difficult to make an estimate on that unless there is further clarity from the US-FDA. You know that we have made a disclosure about Divis Pharmaceuticals right in our public issue time as a person related to us having started that enterprise even before our own project commenced. And we understand from Divis Pharma that they have received a communication from FDA and they would like to audit their facility. And DPPL replied saying that they do not have products for US market and are not ready for any inspection, they do not have any intention of manufacturing any products for US market. So, we do not know why that happened.

Aditya Khemka: And also, in terms of your Unit-1 which is also exports to the US, so we have seen in the past, whenever there are these data integrity led issues, FDA tends to classify all the plants of any given company under that data integrity banner saying that if you are not following data integrity practices in one plant, you may not have that in the other plants as well. So, in your view what is the chance of the FDA extrapolating this issue at Unit-2 to Unit-1 and maybe re-inspecting Unit-1 very soon, is that a possibility you think?

Murali K. Divi: The last inspection we had in Unit-1 was in June 2014 for cGMP. So, yes you are right, in a normal course, there can be an inspection expected during the year. The CAPAs based on the observation at Unit-2 are being implemented at Unit-1, and hence there is a fair level of preparation for any possible inspection of Unit-1.

Aditya Khemka: So given that, what would be the exposure of Unit-1 to the US market as a percentage of total sales, if you could just tell us that?

Kishore Babu: We have broadly mentioned that the rest of 65%, i.e., 35% is the exports from Unit-1 of the total turnover. And of which about 32% is to the North American market.

Aditya Khemka: Okay. So even Unit-1 accounts for 22%.....

Kishore Babu: 32% of 35%. See, the breakup of total exports is 35%, total business breakup between Unit-1, Unit-2 is 35% - 65%. So the exports to the North American market is about 32%. So, 32% of 35% is exposure to the North American markets from Unit-1.

Aditya Khemka: Which is about 10%?

Kishore Babu: Yes.

Aditya Khemka: And lastly if I may, one last question. So, I heard the comment of you guys trying to expand Unit-1 capacity and even Unit-2 capacity to accommodate further growth. Just as a recommendation if I may, what we have seen generally in the past is that these data integrity issues led to import alerts that can take many years, sometimes two years, three years or even five years to solve. And may be working on the Kakinada plant at an expedited pace or an alternate plant site and may be switching products from these two sites to that site may just be a prudent strategy, just a recommendation from our end if you want to take that on record. That's it from me.

Murali K. Divi: Yeah, thank you

Moderator: Thank you, next question is from the line of Girish Bakhru from HSBC Securities.

Girish Bakhru: Just a question on the estimate, given that you had said that impact on the top-line is 5%, have you done a broad analysis of what could be the impact on the margins or the bottom-line?

Kishore Babu: I think we will not be able to give any disclosure on this. And basically the bottom-line is a factor of the product mix, so product to product we need to evaluate. And at this stage, I do not think we will be able to guide on that.

Girish Bakhru: In the non-exempt list, would one assume there will be larger share of custom synthesis in these products and therefore the impact could be higher than what is guided on the sales front?

Kishore Babu: I do not think, the impacted products are just about 5% of our total business. And of course, in that, there would be generics as well as CS components. And in any case, as we mentioned, it is about 5%.

Girish Bakhru: And at this point, I know you talked about the expansion plan, are you evaluating transfer of certain products, although you said non-exempted ones may not be that big in terms of the sales. But are there products which can become big materially in the next few years in terms of the pipeline that you think need site transfer to Unit-1 or something like that?

Kiran Divi: At this point, it is very difficult for us to answer on what steps we will be taking as we are still awaiting to hear from FDA, because our prime goal at this point is to get into the full cGMP compliance and keep Unit-2 going as fast as possible.

Moderator: Thank you, next question is from the line of Rohit Bhatt from Batlivala & Karani Securities.

Rohit Bhatt: Just wanted to check about this clause 99-32 of import alert which was basically issued a day after 66-40 was already issued to you. I mean, probably the status of Divis Pharma Limited must have been at the back of their mind. Just wanted to know, is there any operational link for

business dealings that Divis Pharma Pvt. Ltd has with Divi's? Are you sourcing any intermediates or anything from them?

Kishore Babu: First, I would say on why this 66-40 and 99-32 got mentioned. As soon as we saw the Import Alert we decided first to disclose. The import alert came by way of email to our senior management who were travelling at that point of time when import alert was issued. You know, we have a time zone issue. While we were really surprised to see an import alert, we have been trying to ascertain why 99-32 got mentioned in the import alert and have been trying to get this clarified through our consultants. And we did not want to make a disclosure till we get clarified. As we realized this might take some time, as a matter of prudence, we have decided to disclose this clause as well, which we did the next day. As for the relationship with Divis Pharmaceutical Pvt. Ltd, all these years we have been on record to state in our Annual Reports that there are no transactions between us. It is just that Dr. Divi and Ramana wanted to give a handholding for him to start his enterprise way back in 1992 and we agreed to become directors of the company. And we do not have any similar products and we do not source any intermediates, there are no transactions with Divis Pharmaceuticals. In fact, it is difficult to assume that the recent inspection is triggered by the import alert (issued) to Divis Pharma just because both of us have the same registered office. In fact, when there was a query from the Border Customs, we have clarified to US-FDA at Border Customs in US that these are distinct entities and that Divi's Labs does not have any relationship or transactions with Divis Pharma.

Rohit Bhatt: Because I think, this clarification if it comes or if it is informed to the FDA it might help before the inspection of Unit-1, whenever they do that, I mean if that can be clarified.

Kishore Babu: Noted.

Murali K. Divi: Thank you

Rohit Bhatt: And just one last thing, could you be able to give what is the contribution of intermediates to Divi's business mix? I mean, you generally talk about CCS and Generics, how much would be the contribution of intermediates?

Kishore Babu: We would not disclose that number as such. It will be there more in CS and definitely in generics also. But as Dr. Divi has already mentioned that we are in dialogue with our customers and combined with the customers, we would approach FDA for exemption of any criticality of a component required.

Moderator: Thank you. We will take our next question from the line of Ranbir Singh from Systematix Shares. Please proceed.

Ranbir Singh: One related to that remediation cost, so to your assessment, what may be the cost going forward?

Kishore Babu: Well, there would be expenditure by way of consultants' fees and there could also be some capital expenditure towards any instruments or equipment that needs to be augmented. I do not see this is going to be any significant.

Ranbir Singh: And the revenue breakup which you have given which is exposed to the US market, so majority of it is related to generic API or custom synthesis, if I have to breakup this?

Kishore Babu: That is a separate category which we have been disclosing quarter-on-quarter, as you know that about 55% is generics and 45% is custom synthesis or whatever we have been disclosing in the market. And more so, I gave a breakup between the two units that 60% - 65% is from Unit-2 and 35% - 40% is from Unit-1, and I also gave a breakup of what is the exposure to the US market from these units.

Ranbir Singh: Sir, US FDA inspections last happened in Unit-1 also had some minor observations?

Kishore Babu: Dr. Divi's introduction says that, ….. with nil or minor observation for the last 11 inspections, for both the Units, highlighting that this kind of observations and escalation has not been ever seen before.

Moderator: Thank you. Our next question is from the line of Nikhil Upadhyay from Securities Investment Management.

Nikhil Upadhyay: Sir, two questions. Post 483 in December, have we received or have we seen any client or other agency inspections and if you can share, the outcome of those inspections or anything?

N. V. Ramana: Post the 483, we have notified all our customers and some of them have definitely sent their people to come and see both the reason for the observations and our response. So people have visited and verified.

Nikhil Upadhyay: Okay. But was their response similar to what FDA has seen or if you can share anything on that?

N. V. Ramana: I think this, let's say, is customer confidential. So they have come, they have checked. And at this stage, I do not think I can say or clarify what you asked, specific to the customer.

Nikhil Upadhyay: And just regarding the first observation on the 483 which was regarding this usage of inhibit integration, I just wanted to understand, because as you mentioned we had five and six inspections earlier also and I do not think we would have changed the processes too much. So, the same process we would be following earlier also, so is it something that we have changed in the interim as a result this came out as a major event for the FDA?

N. V. Ramana: See, the standard-operating-procedures have been there and whatever have been followed, have been followed. So there is no change in the interim or anything like that.

Nikhil Upadhyay: And lastly sir, in the exempted product list, there are two intermediates, BOC and Ester, which are for Ritonavir. So, has the FDA taken (exemption), because intermediates……., I do not think largely if we are supplying the intermediates, we do not need an FDA approved site for it. So, is it something which the FDA has taken a different course this time that only these two or three intermediates would be allowed and other wound not be allowed?

Kiran Divi: These are advance intermediates which require cGMP compliance.

Moderator: Thank you. Our next question is from the line of EK Sundaram from DHFL Primerica Mutual Fund.

EK Sundaram: I have two questions and one request for Divi's management. One is, as far as the nutraceuticals is concerned, does this notification from US-FDA, in any way, affect the sales of nutraceuticals, is it different or is it the same?

N. V. Ramana: As you can see, the import alert relates to drugs. And nutraceuticals is a different category. At this time, we think it does not impact. But we would not make those assumptions, we are discussing with the consultants and they are going to advise us on this.

EK Sundaram: Sir my second question is about this clause 99-32, just for my understanding, is the records for the manufacturing processes, are they maintained electronically or are they maintained manually or both?

N. V. Ramana: It is a combination.

EK Sundaram: And the US FDA obviously had access to both, right?

N. V. Ramana: Yes.

EK Sundaram: Sir, the third thing is a request, this conference call actually is doing a lot to clear many doubts. So, my request to the Divi's top management is, at least once in a year if you can have an investor meet or something like that, you need not do it on a quarterly basis but once a year if it is done, I think it would go a long way in clearing the doubts from an authentic source. So this is my request to the Divi's management.

Murali K. Divi: I think we traveled with all of you and our valued shareholders of the company in the last 15 years. We have been driving it, and myself and the team have done excellent job and we have

been sharing our things during the AGMs. And yes, I think your valuable input of asking us to conduct once a year, I think if this kind of things are happening, yes, we will consider that.

Moderator: Thank you. Our next question is from the line of Rakesh Naidu from Haitong Securities.

Rakesh Naidu: I just wanted to know, if you have heard from any other regulators post US FDA inspection on the compliance status?

Murali K. Divi: No. Post-FDA inspection, I think I did mention that the Canadian Health Authorities have asked for the information pertaining to the 483 issued by US-FDA and we have filed the required information with Canadian Health on the lines of response filed with the FDA.

Rakesh Naidu: And my second question is, what in your opinion should be the timeline to implement the corrective measures to be in a full compliance with what the US-FDA has requested, how much time do you think is required by you?

N. V. Ramana: See, as I mentioned before, the response to the 483 observations have been filed in time and we have filed an update and another update will be going now. So, we will have to await information from US-FDA after they have finished the evaluation of our response. So, unless we hear from FDA, we would not be able to say what else is expected from us.

Rakesh Naidu: And sir one final question, what is the scope to shift the non-exempted list of products to other facilities?

Murali K. Divi: Kiran has already clarified to the question saying that right now the concentration is or the prime goal is to get the Unit-2 into full cGMP compliance as early as possible. That is the focus because we already got exemption for majority of our large volume products. And as Kishore mentioned that the impact is about 5%. So, the concentration is mainly and the prime goal now is to get everything into compliance. That is the focus.

Moderator: Thank you. Our next question is from the line of Rahul Sharma from Karvy Stock Broking.

Rahul Sharma: Just wanted to clarify, we have around 43% of our revenues coming from Europe, how much is the contribution of Unit-2 and Unit-1 to Europe, sir?

Kishore Babu: We have already seen the exposure from Unit-2 to North American market is 22 - 23%. And I have also mentioned that overall company's exposure is 32%. So 10% will be from Unit-1.

Rahul Sharma: Unit-2 or Unit-1?

Kishore Babu: Unit-2 is 22 - 23% to the US market, so rest of 10% is from Unit-1.

Rahul Sharma: But Europe, what is the exposure to Europe?

Kishore Babu: I have given to the earlier caller that 65% is the sales from the Unit-2 and 35% is from Unit-1. If 40 - 45% is the overall exports of the company to the Europe, so 45% of 35% you need to factor as sales to Europe.

Rahul Sharma: And sir, another thing was, due to this 5% impact which is going to impact our revenue growth in FY18 and FY19, what is our first initial estimate on the revenue guidance which probably we could look at in FY18 - FY19, sir?

Kishore Babu: We have been typically guiding a growth of about 10% in the normal course across FY18 as well as FY19. Now, we need to factor this impact of 5%.

Moderator: Thank you. Our next question is from the line of Harith Ahamed from Spark Capital.

Harith Ahamed: Sir, I was looking at capacity break-up across your units as disclosed in your FY16 annual report, and it appears that Unit-1 accounts for roughly 20% of your total capacity in cubic meters and Unit-2 accounts for 80%. Now, you just said that the sales contribution from Unit-1 is 35% and the remaining 65% from Unit-2. Since both the facilities are running at near 90% capacity utilization, it appears that Unit-1 has a much better sales mix versus Unit-2. Can you help us understand that?

Kishore Babu: See, all these capacities perhaps are being seen with reference to the reactor capacity that is available. The cycle of manufacture of each one product will have a different time cycles or the reactor capacity requirement. So you cannot factor just the reactor capacity to the sales values.

I would request any other caller to go offline and send us any queries by mail to me, because we have completed the deadline.

Moderator: Thank you. Ladies and Gentlemen, I would now like to hand the conference over to Mr. Kishore Babu for closing comments. Over to you, sir.

Kishore Babu: On behalf of Divi's Laboratories, I appreciate your time for attending the conference call and clarifying your queries with the senior management of the company on the FDA inspection and hereby conclude this conference call. As we get further clarity and make progress with the remediation efforts, we will update on the developments. Any queries from the callers who are not able to reach us, I would request them to mail us the queries so we can reply offline. Thank you so much.

Moderator: Thank you, Mr. Babu. Ladies and Gentlemen, on behalf of Divi's Labs, that concludes today's conference call. Thank you all for joining us, and you may now disconnect your lines.