Corporate Participants

Dilip Shanghvi
Managing Director, Sun Pharmaceutical Industries Ltd.

Moderator: Ladies and Gentlemen, Good Day and Welcome to the Sun Pharmaceutical Industries Conference Call. As a reminder, all participant lines will be in 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 an operator by pressing '*' then '0' on your touchtone phone. I now hand the conference over to Mr. Nimish Desai of Sun Pharmaceutical Industries Limited. Thank you and over to you, sir.

Nimish Desai: Thank you. Good evening and thanks for joining us on this call. I am Nimish from the Sun Pharma investor relations team. We hope you have received the press release on the Halol facility that was sent out earlier in the day. This is also available on our website.

We have with us Mr. Dilip Shanghvi – the Managing Director of the company.

The discussion today might include certain forward-looking statements and these must be viewed in conjunction with the risks that our business faces. You are requested to ask two questions in the initial round. If you have more questions you are requested to rejoin the queue. I also request all of you to kindly send in your questions that may remain unanswered today. I will now hand over the call to Mr. Shanghvi.

Dilip Shanghvi: Thanks you for joining us for this call on a Saturday evening. As you all are aware, we have received a warning letter for the Halol facility yesterday. While more clarity on this will emerge going forward, we continue to cooperate with the US FDA and undertake any additional steps necessary to ensure that the US FDA is completely satisfied with our remediation of the Halol facility.

Let me now share with you, our understanding of why this event happened and what will be the way forward.

Our initial reading of the warning letter indicates that it is based on the form-483 observations issued in September 2014. Over the next few days, we will try to understand this in further detail. The issues highlighted in the warning letter are mostly the same that were identified by the USFDA during the last inspection in September 2014, for which a remediation plan is already under implementation since then. We have been providing updates to the US FDA on the progress of the remediation and on issues of product supply.

In terms of the impact of the warning letter, let me highlight that post the September 2014 inspection, the US FDA has withheld future product approvals from the Halol facility. This situation will continue until all issues are resolved and the site comes back in compliance. We are reaching out to our customers in the US to apprise them of the development.

As indicated in the past, there is a robust remediation plan which is being implemented at Halol with the help of external consultants. We expect to request a re-inspection by US FDA upon completion of our remediation commitments. We are also constituting an internal task force to specifically address the issues raised in the warning letter. We will respond to the warning letter with a detailed plan within the stipulated time frame.

We continue to supply products from Halol to meet our obligations to our customers and the patients who use our products in the United States and around the world. Sun Pharma has always ensured that its products are safe and effective and there is no doubt on the safety of our products in the market.

Lastly, let me reiterate that we are pledged to being cGMP compliant and are committed to continuing to supply our customers and patients across the international markets with quality products that meet all specifications and meet all cGMP requirements. With this I would like to leave the floor open for questions. Thank you.

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Moderator: Thank you, sir. Ladies and Gentlemen, we will now begin the Question-and-Answer Session. We have a first question from the line of Chunky Shah from Credit Swiss. Please go ahead.

Chunky Shah: I have a couple of questions; first one is how does this warning letter change the supply resumption schedule or the remediation plans, whether we will continue with our existing remediation plan and based on that our supply issues which were there, would that be on track or will this result into a delay into that? Second one is whether we have already transferred Glumetza to any other site?

Dilip Shanghvi: We will continue to focus on addressing all the concerns that were raised in the original form-483 and subsequently in the warning letter. We are evaluating whether we need to significantly or materially augment our remediation plan. But till that time, we continue to supply the products in the market and there will not be any change in what we have shared with you earlier. About

specifically Glumetza, I am not very familiar, but I think our major focus is to bring Halol back in compliance rather than protecting cash flow from each small product. Hopefully, with the effort and the resources that we have at the disposal of both manufacturing and quality organization, our effort is to resolve the compliance issue at the earliest.

Chunky Shah: A follow-up on the first question; so basically does the timeline of the remediation get extended at all because of the new developments of the warning letter or we will still stick to whatever earlier timeline was there and the earlier re-inspection that we had in mind that we will invite FDA on a particular date, will that get shifted because of the warning letter or…?

Dilip Shanghvi: We are studying the warning letter at a level of depth that has not been possible in few hours that we have had with us since the receipt of the warning letter. I am not able to comment whether it changes our basic timeline, but as I have said that since the warning letter is reflecting the concerns which were raised in the original inspection form-483, I think hopefully it will not materially change our timeline.

Moderator: Thank you. The next question is from the line of Kartik Mehta from Deutsche Bank. Please go ahead

Kartik Mehta: Does this impact your FY16 revenue guidance which you gave? Can you quantify the total sales which we have from Halol?

Dilip Shanghvi: This does not change our guidance. The sales to the US from Halol is a high single digit number in percentage terms for our total sales.

Kartik Mehta: So you would mean that for the FY16 guidance number or FY15 which is the last reported number with Ranbaxy as a…?

Dilip Shanghvi: This I am talking about is FY16. It will also not be materially different for FY15.

Moderator: Thank you. The next question is from the line of Sameer Baisiwala from Morgan Stanley. Please go ahead.

Sameer Baisiwala: It has been 15-months since the inspection happened. What in your assessment is the reason why FDA is issuing warning letter now and not any time earlier -- is it dissatisfied with your original remediation plan or was it the execution of it, any color on that would be helpful?

Dilip Shanghvi: It is difficult for me to answer on behalf of the FDA as to what triggered this warning letter. I think we have been working with global experts and subject matter experts on the issues which have been raised. Maybe it is our inability to effectively communicate the extent of changes and extent of remediation that we have done. It is also possible that we thought that some information which we were expecting that FDA will come and look for when they inspect us again, maybe that is something which was expected that we will share with them. We really do not know.

Sameer Baisiwala: I am just curious from your perspective how do you get out of this? If the issue is listed in warning letter are same as they were in 483, I am sure you would have done everything that was required to remediate. So what more additional can you do now or is there scope to improve your remediation which you had earlier undertaken?

Dilip Shanghvi: Those are the things that we will study and we will get greater clarity going forward because whether the remediation commitments that we have made, whether that is adequate, we need to do it faster, we need to do more than what we have done or what we have committed. So these are the issues that we will need to assess and understand, we will also possibly consult with additional subject matter experts who can help us in understanding the current thinking with the FDA. So, I think the idea is to do all of that in the next few days.

Sameer Baisiwala: For the future next 12, 18, 24 months, how much is your dependence on Halol to get new product approvals versus non-Halol size if you were to number of them for the US market?

Dilip Shanghvi: Halol is an important location from which we have filed products. It is the only site from which we have filed injectable products. So to that extent, I expect Halol to be increasingly important site for Sun. So, getting the site back in compliance is our major priority and focus.

Moderator: Thank you. The next question is from the line of Girish Bakhru from HSBC. Please go ahead.

Girish Bakhru: First one again was on the warning letter content wise that is mentioned like if FDA is not happy with the remediation efforts done so far, and if FDA has looked at all the responses submitted so far?

Dilip Shanghvi: It is difficult for me to respond but our initial reading of the warning letter indicates that it is essentially based on the observations in the form-483. So I do not think I can respond to whether they have looked at our responses and if that is not factored into their changes, so it is difficult for me to respond to the second part of the question.

Girish Bakhru: On the timeline, I know you probably will not be able to in a position to share in terms of when you see this situation resolving but going by the statistics if one were to assume warning letter typically take around 12-15-months for resolution, would you say that kind of average timing would work in this case as well or it could be faster than that?

Dilip Shanghvi: We have to look at many things when you look at statistics of time to resolution. So, most of the time that when you said 12-15-months of resolution, that is because the time between the inspection and warning letter sometimes is not as high as what it has been in this case. So, maybe a significant part of the remediation we have done. Because clearly I do not think we will have to redo all the remediation, we may have to augment some of the remediation. So it may not take 12-15-months is what is our sense.

Girish Bakhru: One clarification; I am just trying to understand FDA's action at this stage without having done reinspection. Does it come from the fact that they have to act on the certain stipulated time or how does it work?

Dilip Shanghvi: I think difficult for me to respond on behalf of FDA. What we know is what we have shared with you.

Moderator: Thank you. The next question is from the line of Darshan Mehta from ET Now. Please go ahead.

Darshan Mehta: Which are the products in the future pipeline that are filed from Halol and how many of them have been transferred to any other site? Also, from the time that the issue you got a Form 483 in the Halol facility, have any other plant been inspected by the FDA?

Dilip Shanghvi: I can share with you one information which is in public domain that Imatinib which was filed out of this site, we have received the approval for that product out of our Cranbury site in the US. As to intervening period between the Halol inspection and today, almost all our major US manufacturing sites both for dosage forms as well as API have been inspected by FDA without significant adverse observation.

Darshan Mehta: Also, if you can tell us now since then you are not getting any approvals from Halol currently, which are the other plants that you are looking to transfer products, so which are the other important plants that will be helping you to meet the guidance or from where sales will actually come in now?

Dilip Shanghvi: Our guidance factors delayed approvals out of Halol. Our focus is to bring Halol back in compliance rather than focusing on transferring products at this point of time.

Moderator: Thank you. The next question is from the line of Manoj Garg from Health Co Please go ahead.

Manoj Garg: I am a little bit confused, I was hoping that you could provide some clarity. So basically you have been undergoing remediation including third-party consultants for a little bit upward 15-months. We are seeing the warning letter essentially cite the same original observations. So, do the team of the agencies not happy with the piece of remediation so we should expect maybe a pickup in terms of how quickly you are going to be acting going forward?

Dilip Shanghvi: It is difficult to respond to behalf of FDA but the responses that we are giving and the approach that we have taken for issues which FDA has identified, our focus will be to try and understand if we need to augment whatever commitments that we have made, make it faster. So, over the next few days, we will need to develop better understanding on this. We will also consult with additional subject matter experts to develop a more holistic understanding of the current expectation.

Manoj Garg: In the recent past, looking at some other warning letters that some of your peers have gone in, almost all of them the FDA cites system wise deficiencies, I was wondering in your warning letter do they talk about any system wise issues and do you have any concerns for any of the other plants?

Dilip Shanghvi: Since our form-483 observations are in public domain. And we are sharing with you that the warning letter is essentially reflecting the observations of the original inspection and the original inspection had no system wise issues. There were issues raised about the sterility assurance and validation of the sterility system and all of those issues but not system wide compliance issue.

Manoj Garg: In the past from warning letters we have seen some level of coordination between the US FDA, the Canadian agencies and rest of the world. Can you update us on the last time I guess the European or Canadian agencies had inspected the plant?

Dilip Shanghvi: I do not have the current information that I can very realistically respond but my own understanding is that between the last inspection and today, something in excess of maybe 10 or 12 regulatory inspections for Halol have been done. It would include European agency. I am not sure whether the Canadian agency has also inspected, but as I said that almost all our major US supplying sites, both in the country as well as outside the country have been inspected over last 14-15-months and they have passed without any major observation, hence those facilities continue to be in compliance and we continue to receive approvals.

Manoj Garg: Last house-keeping question; will you be releasing the warning letter or should we plan on getting it from the FDA directly?

Dilip Shanghvi: Since the FDA issues a redacted warning letter, we will not know what is it that they will redact. So we have decided not to issue the copy of the warning letter. When it becomes part of the public domain information is the time when we will also if necessary share it with the investors.

Moderator: Thank you. The next question is from the line of Neha Manpuria from JP Morgan. Please go ahead.

Neha Manpuria: Is there any mention in the warning letter of probably having third-party consultants review all our manufacturing sites to make sure the remediation action that you have taken in Halol is implemented across our manufacturing facilities?

Dilip Shanghvi: Actually, when FDA has inspected our other facilities, they themselves in their audit have seen whether we have worked on all our previous inspection observations by FDA. I do not have the exact response to you.

Neha Manpuria: Based on where we are currently, what according to you would be a fair assumption there assuming the remediation implementation that is going on when we can have the US FDA actually re-inspect our facility?

Dilip Shanghvi: We have to reassess whether the warning letter requires any material change in our original plan. If it does not, then our plan was to request for inspection in a period of time, but it is difficult to respond till we fully and comprehensively study the warning letter.

Moderator: Thank you. The next question is from the line of Dhiresh Pathak from Goldman Sachs. Please go ahead.

Dhiresh Pathak: Sir, you highlighted Gleevec which is also in public domain that you site transfer. Any other high profile product that you can share that you site transfer?

Dilip Shanghvi: Other than Gleevec, our focus is to try and get the plant recertified so that we can get the approval from Halol.

Dhiresh Pathak: Is there a number of pending ANDAs from Halol that you can share, provide some color on how many Injectables?

Dilip Shanghvi: We are not splitting ANDAs from different sites.

Moderator: Thank you. The next question is from the line of Manish Jain from SageOne Investment Advisors. Please go ahead.

Manish Jain: I just wanted to know in terms of the Dosage segments which are continuing to be exported to US from Halol. Is it all the Dosage segments like Oral, Injectables, if you can give some insight on that, it will be great?

Dilip Shanghvi: We continue to export all dosage forms.

Manish Jain: From SPARC's perspective, where you already had an approval on Levetiracetam, Latanoprost. What impact of this will it have on those approvals?

Dilip Shanghvi: Till the time the site comes back in compliance, those approvals out of the site will not be available.

Manish Jain: With your permission on at what stage do you think of using an alternate site for those products where every other thing has been done for SPARC products?

Dilip Shanghvi: Anil Raghavan should be able to respond to that, but because all of these are 505(b)(2) filings and when we want to file from a new site, we have to give one year stability data. So it is going to take significant amount of time before maybe a product like Levetiracetam, which is a slow release product, can be transferred. You have to maybe redo bio study and a lot of other additional efforts plus one of the other products require a special manufacturing infrastructure which may not be available with contract manufacturers. So, it is not a very easy decision.

Moderator: Thank you. The next question is from the line of Ajay Tyagi from PTI. Please go ahead.

Ajay Tyagi: I just wanted to understand what are the major issues the US FDA has raised in the warning letter?

Dilip Shanghvi: As I said, the observations that FDA had when they sent us form-483 is the basis on which the warning letter is issued. The major observations in the form-483 were related to validation and compliance of the sterility assurance system like media fill, etc., and also the computer system validation.

Ajay Tyagi: Could you just specify some of the steps that you are taking right now?

Dilip Shanghvi: We are working with subject matter experts to develop a remediation plan so that we improve our processes to ensure that we meet the regulatory agency expectations for all of these concerns.

Moderator: Thank you. The next question is from the line of Manoj Garg from Bank of America. Please go ahead.

Manoj Garg: Typically, when FDA responds and issued a warning letter, they do refer the remedial measures which the company has taken in response of 483, so whether in this warning letter, have they

mentioned anything on those remedial measures which you have submitted, any observations on that or they are silent on that aspect?

Dilip Shanghvi: They would have referred to some of the responses, but possibly not all the responses that we have submitted.

Manoj Garg: So it means that some of the remedial measures which you have submitted probably they have looked at those measures?

Dilip Shanghvi: Correct.

Manoj Garg: Even in the previous comments and even on this call also you have commented that you have taken significant steps in terms of augmenting the facility, digitization, third-party consultants and everything. So just want to understand from your aspect in terms of remedial measures, but more need to be done, any assessments like when probably the capacity constraints kind of issue which you are facing through right now will be over at least from the Halol?

Dilip Shanghvi: It is important for us to keep in mind is it maybe it is also our inadequacy in terms of sharing with FDA as to the extent of remediation that we have done because we may have kept some information with us with a view to share it with the FDA inspectors when they physically inspect. Maybe that is something that we need to share with them as a part of our ongoing response or we may have to do a few things differently, a few things more than what we have done in the past. In next few days we will have a better understanding.

Manoj Garg: With this new development, whether this will change your goal post in terms of inviting FDA for reinspection or it might take some more time?

Dilip Shanghvi: It will take us a few days to understand exactly what changes will be involved as a part of the response to the warning letter, and as we develop that clarity and understanding if there is a material change in our expectation for reinspection, then we will share it with you.

Moderator: Thank you. The next question is from the line of Alok Dalal from CLSA. Please go ahead.

Alok Dalal: Overall Sun Pharma's track record with the US FDA has been mixed. So apart from Halol, the other sites what kind of changes you are making to the systems and processes so that it improves the track record with the FDA?

Dilip Shanghvi: It is a valid observation. Our objective would be that we become compliant with the FDA expectation and also all regulatory expectations from all the facilities by focusing on not only meeting FDA or regulatory compliance but trying and finding a way to what they are expecting. It is a journey but we are committed to pursue it with the complete organizational commitment.

Alok Dalal: How many years are you into this journey – are you more or less half way through or maybe 75%, can you help responding there?

Dilip Shanghvi: I told you that post the inspection at Halol, almost all our major sites have been inspected by the FDA without any major observations. We have worked hard to address and implement the changes so that we do not see Halol type problems in the new sites. So we have to focus on ensuring that we continue to exceed their expectations in all the sites and also find a rapid way to meet FDA expectations for Halol.

Moderator: Thank you. The next question is from the line of Prakash Aggarwal from Axis Bank. Please go ahead.

Prakash Aggarwal: Sir, just trying to understand the remediation plan that you had submitted. How much percentage of work would you have finished by now?

Dilip Shanghvi: Difficult to quantify. So, we have given commitment to do certain work by a certain period of time. We are meeting most of those timelines. But "how much is yet to be done", is difficult to measure in percentage terms.

Prakash Aggarwal: The question because you have done some voluntary supply stoppage. I am trying to understand, the warning letter would that lead to more blockage of supplies so that you do one full end or it is going to be small bits and pieces, that is what I am trying to understand? So going forward we do not expect the voluntary supply disruption that we saw that is unlikely to expand, that is what…?

Dilip Shanghvi: Yeah, that is correct.

Prakash Aggarwal: Just trying to understand, how industry or the distributors, the channel reacts once the pharma company with its sole products which has allowed the existing basket to sell in the US, could we see some market share losses as well, how do we…?

Dilip Shanghvi: I believe that customers will perceive potential disruption as a risk and that may impact our ability to win long-term market share if we are not able to address this in a short period of time.

Prakash Aggarwal: One comment you made of the 10-12 other regulatory inspections been done, did you mention those have been cleared or what has been the status sir?

Dilip Shanghvi: We are in clearance of all the inspections.

Moderator: Thank you. The next question is from the line of Ashwariya Deepak from Reliance Mutual Fund. Please go ahead.

Ashwariya Deepak: What are the top two differences between the 483 and the warning letter because like Dr. Reddy's we find that they have enhanced the scope of the compliance when they were sent the warning and what was there in 483?

Dilip Shanghvi: That is what I am saying again, is that our assessment or early read of the warning letter indicates that the warning letter is essentially based on the form-483 observation.

Ashwariya Deepak: Just one clarification; whether they have tried to increase the scope of all the compliance whatever they have mentioned in 483 versus warning?

Dilip Shanghvi: That will possibly require a much more detail study that whether the expectation is more than that required to resolve the form-483 observations. My own view is that observations in form-483 is the basis on which they would have given the warning, but I do not have ability to say yes or no.

Ashwariya Deepak: I was not able to understand what has triggered this warning because you people are anyway working on the compliance and you are consistently updating them, so what has led them to send the warning letter, any kind of guideline for priority will be very helpful?

Dilip Shanghvi: You should understand that it is difficult for me to answer on behalf of FDA. I can share with you what we have done, which we have shared with you.

Moderator: Thank you. The next question is from the line of Fatima Pacha from ICICI Prudential. Please go ahead.

Fatima Pacha: From the last conversations that we have had is it fair that the original goal post of maybe inviting the US FDA for inspection sometime in Feb-March this year because I remember in April you said that we are looking till the end of FY16, would that be a fair estimate?

Dilip Shanghvi: I do not know and I do not exactly recall whether we would have given a specific date but I think we have of course worked with clear internal dates, but we will study the warning letter in much more depth than what we have done in the last few hours and evaluate whether that makes a material difference in terms of our preparedness for facing the next inspection.

Fatima Pacha: It will be great if you could just tell us the original goal post, was it much of a market feel or you think market feel is a good conservative timeline?

Dilip Shanghvi: I do not think that we have shared the original timeline also. So, difficult for me to confirm or to disagree.

Fatima Pacha: Can you expect that in the quarterly call that we will have in the next 1-1.5-months we would be able to share it or would you have a call in between as well?

Dilip Shanghvi: If that requires materially significant additional effort, then we will share that with you.

Fatima Pacha: Is it fair that in absence of communication it means status quo?

Dilip Shanghvi: No, in the sense that if there is a materiality then we will of course have to share it with the investors, that is what our regulators also expect us to do and that we will follow.

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

Surya Patra: Although you have already indicated that the majority of the remediation duty has not done and we could see kind of minimal kind of activities going ahead but what is the kind of implication on the expenses front one should look at so far as remediation activities would be concerned?

Dilip Shanghvi: I think it is already factored in our expense statement till now.

Surya Patra: So do you see enhanced kind of run rate for that or it should be seeing a kind of decline run rate, how should we…?

Dilip Shanghvi: We have to study the warning letter in detail and understand whether it does require any significant additional effort.

Surya Patra: On the Ranbaxy plant, whether this development will have a kind of meaningful impact or whether it will delay the kind of timeline what we had given about Ranbaxy plant for corrective actions and the potential clearance of those plants?

Dilip Shanghvi: Let us evaluate internally that whether this will require far more resources than what we had originally thought. If it does not, then maybe that also will not change. If it does require then we will reassess our resources and decide. If there is a material change we will share it with the investors.

Surya Patra: Just a clarification; the supply issues on the Halol side, whether the supply to the other RoW market what was that we are doing from Halol, either it would be impacted or it has stabilized already and will not get impacted because of whatever the initiatives that we have been doing or whatever extra activity that we would be doing in Halol?

Dilip Shanghvi: We remain in compliance for Halol site for all the countries that we are exporting to. Our objective is to retain that compliance status.

Moderator: Thank you. The next question is from the line of Kartik Mehta from Deutsche Bank. Please go ahead.

Kartik Mehta: Just trying to understand this from you that do you feel that this time there is a need to move critical Injectable products which you are selling right now from Halol which have been approved to alternative sites?

Dilip Shanghvi: Our current focus is to bring this facility back in compliance. As a long-term practice of maintaining flexibility and supply chain compliance means for us to look at alternate Injectable site for US but that will take time.

Kartik Mehta: So as of now you do not feel there is a need to evoke plan-B to move existing sales?

Dilip Shanghvi: We do not see pressure as on today to move the products to a new site because our focus is to bring Halol back in compliance.

Kartik Mehta: Just trying to understand your statement that if you need to augment your efforts, in Q3 FY15 we had shut the Halol plant for some amount of time as a process of remediation, do you see any such possibility now after the time that you would have studied in terms of extra efforts that you would require?

Dilip Shanghvi: We will study and evaluate whether this requires significant additional resources and efforts. And if it is material then we will share it with the investors.

Moderator: Thank you. The next question is from the line of Kumar Saurabh from Motilal Securities. Please go ahead.

Kumar Saurabh: Sir, in the last call you mentioned that you would not wait for the reinspection for the supply to resume in a complete manner. After early reading of this warning letter, would you stick to your original plan or do you think that you would wait for the reinspections to happen before resuming the supply completely?

Dilip Shanghvi: We continue to supply to the market.

Kumar Saurabh: When you mention that most of your other plants have been reinspected in the past 1-1.5-year time period and no major observations have come through, looking back how do you assess because Halol was one of our major biggest plants, and over there US FDA was able to find certain

issues, but all our other plants which are not as important as Halol, those have been cleared, so is it because the plant was big and the scope of mistakes were more over there, is it the fair assessment?

Dilip Shanghvi: Some of the observations that FDA had made at Halol were observations that we saw for the first time. So once we saw those observations in Halol, we have implemented changes in the other facilities so that when they inspected they saw that we have addressed the concerns that they had in Halol.

Moderator: Thank you. The next question is from the line of Praful Bora from Religare. Please go ahead.

Praful Bora: What portion of our Halol revenues would be from the government supplies? In case of a warning letter, do you think that can get impacted?

Dilip Shanghvi: I do not have details about the US business breakup in terms of government and non-government supplies.

Praful Bora: They have one more sterile plant at Pharmalucence. What would be the current capacity utilization there?

Dilip Shanghvi: Not very significant.

Moderator: Thank you. The next question is from the line of Manoj Garg from Health Co. Please go ahead.

Manoj Garg: A few different questions; just wanted to get some more color on some of the products out of Halol. So one is do you have a general split or idea about how many products are coming out of Halol or on the US drug shortage list?

Dilip Shanghvi: I do not have details but we do supply products out of Halol which are drug shortage list.

Manoj Garg: What that contribution is?

Dilip Shanghvi: Difficult to give a number. Also, drug shortage list is a dynamic list.

Manoj Garg: You had previously stated that Halol is currently trending at about high single digit for fiscal year 2016 contribution?

Dilip Shanghvi: That is correct.

Manoj Garg: This might be difficult to do on a percentage basis because of how your reporting has changed from '15 to '16, but basically just trying to understand, what impact the remediation efforts have had on the offshore revenue at the facility?

Dilip Shanghvi: I do not have the numbers immediately. What I think you are asking is that if we look at turnover out of Halol in this fiscal compared to previous fiscal.

Manoj Garg: Is it flat? Is it down?

Dilip Shanghvi: Even for last year the number will not be very different in terms of percentage.

Manoj Garg: Last year you guys have received an import alert at your Cephalosporin facility. Just want to see is there a general update there?

Dilip Shanghvi: Once we have an update we will share this with you. Only thing which I can share at this point of time is that we had shut down the manufacturing in that facility and we have restarted manufacturing in the facility for other markets keeping all the regulatory agencies informed about our plan.

Manoj Garg: What was the basis for that import alert?

Dilip Shanghvi: There were both cGMP and potential data consistency issues that FDA had seen at that facility.

Moderator: Thank you. The next question is from the line of Saion Mukherjee from Nomura. Please go ahead.

Saion Mukherjee: It has been more than a year now since the import alert is there at Karkhadi and also you have seen Mohali for around a year now. Any update you want to share like how things are progressing, any timelines that you can share on those?

Dilip Shanghvi: Not at this point of time. As we get greater clarity we will share that with you.

Saion Mukherjee: You mention that the priority is resolution of Halol rather than looking at site transfer. But you did mention earlier that some of the high value products like Gleevec were site transferred. Is it like dependent on formulation like Extended Release or Injectables where there is greater difficulty and Oral Solids or something which you would continue to look for site transfer, would that be a right way to look at it?

Dilip Shanghvi: Imatinib was a time dependent potential cash flow opportunity. It was necessary to transfer.

Moderator: Thank you. The next question is from the line of Vikas Dandekar from Economic Times. Please go ahead.

Vikas Dandekar: Two questions; one of the questions is about the warning letter. Is there any mention of any global audits to be done on other manufacturing sites because some of the warning letters we have seen FDA asking companies to do that? Second one is about because the revenues will be impacted as you have mentioned in July because of this Halol issue. I was just wondering, what will be the alternatives that the company will look at in terms of shoring up revenues in the interim period?

Dilip Shanghvi: On the first question, our initial read of the warning letter is that we have not seen any global third-party audit requirement as a part of the warning letter. At the same time as I explained between the Halol inspection and today, almost all our major US supplying sites have been audited without any major observation. So that is the response to your first question. To your second question, earlier I also mentioned our major focus is on getting Halol recertified and at the same point of time, the current status of Halol is part of our consideration for the guidance that we have shared with investors.

Moderator: Thank you. Ladies and Gentlemen, due to time constraints that was the last question. I would now like to hand the floor back to Mr. Nimish Desai for closing remarks. Thank you, and over to you, sir.

Nimish Desai: Thank you, everybody for joining this call. If any of your questions have remained unanswered, do send them across and we will have them answered.

Moderator: Thank you. Ladies and Gentlemen, on behalf of Sun Pharmaceutical Industries Limited, that concludes this conference call. Thank you for joining us. You may now disconnect your lines.