INDIAN DRUG MANUFACTURERS' ASSOCIATION

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PARTNERS IN GLOBAL HEALTHCARE

11th March 2014

Mr.Altaf Lal
US FDA Director
India Office
U.S. Food and Drug Administration
Office of International Programs,
India Office, U.S. Embassy
Shantipath, Chanakyapuri,
New Delhi – 110021

Dear Sir,

As you are aware, IDMA is the National Association of Pharmaceutical Manufacturers' in India, having around 700 Members representing Small, Medium and Large Sectors. At present, IDMA has 71 Members having 174 facilities registered with US FDA.

We would like to submit the following to you for your kind consideration.

1. GDUFA:

The GDUFA has been introduced with the objective of providing user fees for FDA to ensure timely review of applications of generic drugs and to supplement the costs of reviewing the generic drugs applications and inspecting facilities. It was expected that with the introduction of this fee, the average time required to approve the applications would be substantially reduced. However, it is observed that the timelines are still very high going up to 36 months.

The reduction in timeline should be brought about to ensure speedy launch of generic products.

GDUFA Fees at a glance:

	FY 2013	FY 2014
API DMF	$ 21, 340	$ 31, 460
ANDA	$ 51, 520	$ 63, 860
Facility Fees API (Foreign)	$ 41, 458	$ 49, 515
Facility FDF (Foreign)	$ 1,90,389	$ 2,35,152

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A reduction in the fees also should be considered since the fees is found be very high for medium size companies. It can be an entry barrier for them, which in turn can result in reduce competition for supplying to USA. This could result in a monopolistic situation and can prevent competitive price.

2. USE OF ANCILLARY SERVICES:

Sometimes the manufacturers use the support of ancillary services like sterilization. The facility of these service providers is being audited by US FDA which is in order. However, the FDA expects these service providers also to pay the facility fees of $ 230,000. Since the service providers depend upon the job work order charges their earnings do not permit them to pay such a huge fee, particularly in the absence of the actual commercial work.

US FDA should consider exemption of such services from the fees.

3. TIMELINES FOR ISSUE OF EIR:

It is observed that the time taken for issue of EIRs after submission of responses to 483s is very high. It will be helpful if the timelines are brought down to below 6 months. For this purpose Inspectors may be empowered to decide facility GMP acceptance. Further, harmonization between field inspectors & HQ would help reduce the timeline.

4. REGULATORY COMPLIANACE ISSUES - INDUSTRY ENGAGEMENT WITH FDA

We are aware of the recent failures of some of the Indian companies in complying with the GMP requirements and the regulatory actions initiated by the FDA.

IDMA has taken a serious note of these developments and is aware of the far reaching impact it has on the image of the Indian pharma industry. We are greatly concerned about the adverse publicity created in the minds of common people and regulators regarding the compliance ability of all the Indian Pharma companies in general.

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We believe that, while the issues are similar to those seen in companies across the world, it is time that the Indian industry approaches the issue with a learning mindset against a victim mindset and use this opportunity as a catalyst for change to bring in required improvements in the management of quality. This is also necessary from the point of view of building our abilities to deal with ever increasing pressures of cost and regulatory compliance and to be able to deliver quality medicines keeping the ultimate objective of patient safety in mind.

We understand the ultimate responsibility of quality of the product lies with the senior management.

We sincerely believe that an active engagement of the senior leadership of the industry through IDMA with US FDA will help remove some concerns on either side. We understand that QUALITY IS TOP DRIVEN, therefore believe that such engagements by FDA with the industry leadership will help the industry to adopt Quality systems and risk- based approach in management of quality and will create a quality culture within the industry.

We therefore request to organize participative discussion programs between the industry & regulators and initiate education programs for the senior management team engaged in ensuring quality of product. This will greatly motivate the industry to come forward for an active engagement with the regulators to find a long term remediation plan for remaining in a state of compliance.

IDMA will be happy to work with you in accomplishing this task.

With regards,

S V VEERRAMANI
PRESIDENT

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