https://doi.org/10.48047/AFJBS.6.12.2024.4709-4724

African Journal of Biological Sciences

Journal homepage: http://www.afjbs.com

Research Paper Open Access

Impact of USFDA Warning Letters on Economic Growth of Indian Pharmaceutical Industries

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Article History

Volume 6, Issue 12, 2024

Received: June 10, 2024

Accepted: July 5, 2024

doi:

10.48047/AFJBS.6.12.2024.4709-4724

Abstract:

The drug companies which sell their medicines in the United States are expected to adhere to the regulations which are entailed by the FDA. The manufacturing units which are engaged in the supply of drugs are frequently inspected by the FDA. Common issues for pharmaceutical industries around the world (including US and India) include inadequate or poor quality systems implementation, data integrity issues, inadequate validation of various processes used in manufacturing or testing, and product contamination. In any region, some drug manufacturers meet US requirements, while others do not. When USFDA determine that there are significant violations at pharmaceutical industries, USFDA take appropriate action to protect the public health through issuing waring letters(WLs) and enacting import alerts to the drugs manufacturing units resulting the financial loss. The WLs not only impacts particular industry but it has direct implications on society where the lot of human being earnings are directly or indirectly depends on the pharmaceutical industries. The

Indian pharma firms need to persistently evolve with the variations in the global regulatory compliances and accordingly adjust cost and resources to adhere to those standards. The overall economical impact of issued WLs on the pharmaceutical industries are to be studded in the article.

Keywords: Warning letter; Import Alert; economical impact, global pharmaceutical industries

Introduction

The US FDA (Food and Drug Administration) is the agency responsible for regulating the pharmaceutical market in the US, aiming to safeguard the health safety of the consumers. The Federal Food, Drug and Cosmetics Act is the basic food and drug law followed in the country.

The United States is the world's leading pharmaceutical market. The US pharmaceutical industry, as the largest, most diverse and globalized industry, is the economy's most competitive and vital sector. Therefore, exporting to the US is a great opportunity that is leveraged by many nations, and to verify the quality standards of medicines, the US FDA was created.

Every pharmaceutical drug marketed in the US has to pass through an approval process, which comprises four stages, viz. pre-clinical, clinical, new drug application review and post marketing. The various types of applications that need to be submitted to the US FDA for drug development and approval include:

- New Drug Application (NDA)
- Investigational New Drug Application (IND)
- Abbreviated New Drug Application (ANDA)
- Over-the Counter Drugs (OTC)
- Biologic License Application (BLA)

NDA is the primary means by which a drug sponsor puts forward to the US FDA for approval of marketing and sales of the drug in the United States. The entire information and data collected while the animal studies and human clinical trials are conducted constitute a part of the New Drug Application

According to the Federal Law, the marketing application of a drug must be approved, before it can be transported or distributed across state lines. Nevertheless, the sponsor of an investigational drug is likely to ship the drug to clinical investigators across various states. So, the Investigational New Drug application is the means by which a pharmaceutical company acquires the permit to ship an experimental drug across state lines (typically to clinical investigators) prior to the approval of marketing application of the drug. The three types of INDs include an Investigator IND, Emergency Use IND and Treatment IND.

For marketing a generic drug, companies need to submit the Abbreviated New Drug Application to the FDA to gain approval. These applications are referred to as ‘abbreviated’

as there is no compulsion of incorporating the preclinical (animal) and clinical (human) data to demonstrate safety attributes. The matter of concern for the drug companies is to confirm scientifically that the performance of their product is comparable to that of the innovator drug.

Over the counter drugs, which refer to the drugs which are available to patients without the need of a prescription, constitute a substantially important segment of the American healthcare market. There exist greater than 80 therapeutic categories of OTC drugs, extending from drugs for the cure of acne to weight loss. CDER's Office of Drug Evaluation IV is essentially responsible for the assessment of the OTC drugs. FDA evaluates the active ingredients and the labelling of more than 80 therapeutic varieties of drugs such as analgesics or antacids, rather than reviewing individual drug products. FDA has developed an OTC Drug Monograph for each category of these drugs, which is published in the Federal Register. Firms undertaking the manufacture of biologics for sale in interstate commerce are expected to hold a license for the product. These products receive an approval for marketing under the provisions of the Public Health Service Act. The application requires

Regulatory Compliance

Regulatory compliance has emerged as a critical challenge for the pharmaceutical industry, particularly in the regulated markets. Noncompliance is cost intensive, and may expose the companies to revenue losses, reputational risks, patient safety issues, criminal sanctions, and can jeopardize the future of the entire business unit. Compliance issues facing the pharmaceutical industry include government policies, drug safety, counterfeiting, information security and privacy, intellectual property protection, corruption and adulteration, and other third-party risks.

Under such a scenario, meeting the evolving regulatory stipulations such as Current Good Manufacturing Practices (cGMPs) should be given prime importance by the pharmaceutical companies. Along with addressing the emerging legal requirements, the companies need to lay emphasis on following the policy of substantial compliance and risk management. The Indian pharma firms need to persistently evolve with the variations in the global regulatory compliances and accordingly adjust cost and resources to adhere to those standards.

The pharmaceutical firms should be facilitated with an updated repository enumerating regulatory requirements notified by each country's regulatory organisation. The repository can be formulated in a manner that lists down the common requirements as well as the variations in standards, such that minimum set of regulatory adherence can be identified to address the compliance across various global agencies. For ensuring the compliance to standards, skill development of various stakeholders is crucial. Preparedness and proficiency in documentation and following statistical techniques as per regulatory requirements are also of considerable importance in this regard. Moreover, to demonstrate and justify that the manufacturing process being applied by the firm is in compliance with good manufacturing

practices, it is essential for them to have a comprehensive record of their production information, which can be presented to the inspectors and auditors.

Warning Letter:

The manufacturing units which are engaged in the supply of drugs are frequently inspected by the FDA. At the completion of the inspection, if the investigator concludes that there exist violations of the Food Drug and Cosmetics Act, then a FDA Form 483 is issued to the management of the concerned firm. The FDA expects a response to the Form 483 observations within a period of 15 days. In the circumstance when the FDA is unsatisfied with the response furnished by the manufacturer in reply of the Form 483, then the FDA might issue a warning letter to the firm.

Import Alert: FDA Import Alert signifies that the product does not comply with FDA laws and regulations. As a result, the products will be detained at the border without physical examination, as there exist adequate evidence regarding the regulatory noncompliance of the product.

Import Alert:

This import alert represents the Agency's current guidance to FDA field personnel, regarding the manufacturer(s) and/or products(s) at issue. This alert is applicable when an evidence exists related to the marketing or promotion of unapproved drugs, to individuals residing in the United States. In this circumstance, the products should be considered for detention without physical examination.

Table 1: Implications of Violating GMPs

Business Loss	Issuance of warning letters can lead to product recalls or import alerts, as well as a fall in the stock prices of listed companies
Reputational Damage	List of companies violating guidelines are posted on a regulator's website, making the information publicly available, which can be further picked up by the media, thereby tarnishing the company's reputation
Regulatory Influence	Additional inspections can be carried by other regulatory bodies or customers tarnishing the company's reputation
Competitive Disadvantage	Competitors can leverage this opportunity to enhance their market share
Diversion to Remediation and Increase in Attrition Rate	Diversion of management and employees' attention from their daily activities, to focus on Corrective Action and Preventive Actions. The lengthy remediation process tends to cost time, money and often loss of talent

Source: Analysing the State of Data Integrity Compliance in the Indian Pharmaceutical Industry, EY

Indian Pharmaceutical Industry

India is a prominent and rapidly growing presence in global pharmaceuticals. It is the largest provider of generic medicines globally, occupying a 22% share in global supply by volume, and also supplies 64% of global demand for vaccines. India ranks 3rd worldwide for production by volume and 14th by value. India is the source of 60,000 generic brands across 60 therapeutic categories and manufactures more than 500 different Active Pharmaceutical Ingredients (APIs). The country is home to more than 3,000 pharma companies with a strong network of over 10,500 manufacturing facilities. The domestic pharmaceuticals market turnover reached $20.03 bn in 2021, up 9.3% from 2018.

Chinese Pharmaceutical Industry

The pharmaceutical industry of China is the second largest market in the world and the largest among the emerging countries. The pharma industry is valued at USD 135 billion in 2018 and is projected to touch USD 175 billion by 2022, with an annual growth rate of 6%. There are nearly 2000 pharma companies and over 5000 drugs manufacturers. The pharma companies in China are primarily involved in the production of generic medicine, active pharmaceutical ingredients, therapeutic medicines and traditional Chinese medicines. Over 90% of drugs registered in China are generic by nature. In the next decade, the global position of Chinese pharmaceuticals is likely to incline towards R&D from manufacturing.

Russian Pharmaceutical Industry

The pharma market of Russia is expected to touch USD 42 billion by 2022 with an annual compound growth rate of 14%. The domestic pharmaceuticals market of Russia is dominated by generic medicine, accounting to 70% of the Russian pharma industry.

Brazilian Pharmaceutical Industry

The Brazilian pharmaceuticals market is projected to touch USD 40 billion by 2022 with a CAGR of 7%. The market share for generic medicine in Brazil is over 33% in 2020. The focus of pharma companies in Brazil is shifting from generic medicine to innovative research.

South African Pharmaceutical Industry

The pharmaceuticals industry in South Africa is valued at USD 7 billion in 2020 with a CAGR of 9.2%. The generic medicine share in the South African pharma market is over 60% and the remaining 40% share is of originator drugs.

GCC Countries

The pharmaceutical industry in the gulf is still in the early development stages compared to international standards. Despite that, it is changing through reform and simplifying government regulations, increasing its efficiency and expanding the infrastructure of health care.

Population growth in the GCC will be a key growth driver for the pharmaceutical sector. Population is anticipated to expand from 37.5 million in 2021 to nearly 50 million in 2020. High levels of urbanization and a strong expatriate presence also support pharmaceutical sales growth in the region. Population aged 60 years and above is projected to increase from 1.9 million in 2012 to 17.8 million in 2050.The elderly population forms a big slice of the overall pharmaceutical spending in the GCC and will also drive growth.

The size of the pharmaceutical industry reached USD 8.5 billion by the end of 2012, compared to USD 7.7 billion in 2011. Saudi produces 59.4% of medicine in the region, followed by 18% in UAE, 9.2% in Kuwait, 5.6% in Oman, 4.5% in Qatar and Finally 3.1% in Bahrain. Health care spending in the GCC will increase as the sector grows, which will lead to a decrease in the percentage spent on pharmaceuticals compared to the total health care spending to match those of the developed world, expecting a decrease from 14.3% in 2010 to 12.4% by 2021.

Literature Review:

According to a recent blog by the USFDA, quality issues have been a major challenge for Indian Pharmaceutical sector **(USFDA, 2021)**. More than 42 warning letters have been sent to the manufacturing units last year. Since 2012, the USFDA inspections have been doubled in India and China, from 11 percent to 20 percent **(Export-Import Bank of India, 2020).** Apart from the quality related problems, the USFDA has additionally recognized the data integrity downside with the drug companies in India. As per the examination reports by the USFDA and MHRA over the previous few years, varied warning letters have been issued to organizations for lack of documented educational program as well. Further, there should be zero tolerance by the prime organization authorities to any non-compliance and ought to be cross practical coaching by the external consultants on the compliance matters.

The study by (**Bhatt et al.2012)** provides an insight on the inspection of Indian sites by the FDA which is still a huge challenge since Indian regulators use low stringent methods for audits and inspections, hence they underestimate the inspections carried out by the FDA. It has been reported that the inspections carried out by Indian regulatory bodies in the past have been inconsistent and moreover, duration of each inspection has also been insufficient to cover non-compliance. Inspections of clinical sites are made to safeguard the human rights, well-being, and safety of the participants involved in the FDA-regulated clinical trials, also to verify the reliability and accuracy of clinical trial information defer to the FDA, to evaluate the backup of clinical research, and to judge the compliance with the FDA's regulations which prevails the techniques of clinical trials.

However, **Patel et al., (2012)** have been reviewed to identify the challenges that the FDA faced as a result of limited resources available. The study highlights that the GDUFA fees

will facilitate the global inspections and provides the speedy and timely review of the generic applications. It also pointed out that the GDUFA statute is a ground-breaking for the generic industry and the main subsidy for American buyers, as it will step-up the market admittance of those drugs that are tiny in stock with the improved quality, consistency, thereby resolving the problem of drug shortages.

Additionally, a study by **(HDFC Bank Investment Advisory Group, 2017)** also highlight the increased cases of the big companies in India facing compliance issues like warning letters by the FDA and the surge of warning indicative of lacking implementation of cGMP standards in Indian Industry. Frequent inspections by the USFDA on the global facilities lead to the consistent and improved quality of medicines in supply.

The study conducted by **Deloitte, (2015)** has shown that India today have about 546 facilities approved by the USFDA, 857 facilities approved by UK MHRA and 1,295 facilities approved by the WHO-GMP. To manage such large number of facilities and its compliance standards, The USFDA has setup two local offices with the investigators in India to carry out the inspections. Many instances of the non-compliance have been found among Indian Pharmaceutical Industry pertaining to the manufacturing practices, data management, and quality control practices. In December 2021, three (3) Pharma companies had received the warning letters.

From the survey, it has been pointed out that most of the compliance challenges are typically due to the shortage of skilled resources, which might hamper the company's growth. Deloitte, (2015) it is important for the companies to work together with the regulatory bodies so as to set-up the training and the development courses to train the professionals. For this purpose now MNCs have established alliances with academic institutions for the research endeavors and the faculty development. But the recent the regulatory actions taken by the USFDA have brought these issues so as to take necessary actions in order to maintain the forthcoming compliance requirements. These compliance issues have greatly affected the Pharma stocks. It has been found that in the last one year BSE Healthcare has declined close to 4 percent.

Analysis, discussion and conclusion

An overview of Global Pharma Industry & India's Role Pharmaceutical industry globally during the year 2020 has been a bit sluggish. However, India's Pharmaceutical exports during Fy-21, has recorded a growth of over 18%, which happens to be the highest during the last seven years. Global market has recorded a turnover of $ 1265.2 billion during the calendar year of 2020(Source: Iquiva report on Global Medicines & usage trends) and has grown by just 1% with an incremental value of $12 bn. General grouping of different markets constituting global market is shown in the table below [https://pharmexcil.com/uploads/annualreports/17thAnnualReport.2021Final.pdf]

Group	**$ bn**

Developed Market	959.5
Pharma Emerging (India is a part of this)	290.8
Rest	15
Global market	1265.3

In the next Five years Global market is forecasted to grow at a CAGr of 3-4% and touch $1,600 billion by 2025,which would be an increase of around $ 350 billion in value.

India's Role in Global Pharma

India is predominantly a generic Player. India during Fy-21 has exported $18.85 billion with a growth of 19.53% which is over six times the global generic estimated growth rate. India's Pharma Industry during 2020-21 has touched $ 49 billion (domestic and Exports). India's Pharma exports during 2020-21 was $24.47 billion comprising of Bulk Drugs, Finished dosage formulations, Ayush& Herbals &Surgicals . India's Pharma exports contributed 8.38% of Merchandise exports. Drug formulations & Biologicals is the second largest Principal commodity being exported by India. Eight of India based companies feature among top 20 Generic companies in the world based Calendar year of 2019 turnover. They are as follows. (Sourced from generics bulletin/informa Dated December 2020).

India Based Companies Featuring among top 20 Generic companies $ Million			
S.No	**Rank**	**Company**	**Turnover $ Million**
1	6	Sun Pharma	4539
2	8	Aurobindo Pharma	3257
3	11	Cipla	2360
4	12	Dr.Reddy's Laboratories	2311
5	13	Lupin	2135
6	14	Intas	2108
7	16	Zyduscadila	1692
8	20	Glenmark	1471

India's Pharmaceutical industry during 2020-21 has produced $40.85 billion worth of finished dosage forms of Generics, out of which $ 18.85 billion has been exported and is self-sufficient as far as generic formulations are concerned. However, India Imported Bulk Drug & Drug Intermediates (Mostly Lower intermediates) to a tune of $ 3841 million.

India is the largest exclusive generic exporter in the world.

USFDA has Granted 1438 market authorizations in Fy-21. Out of these India based companies have bagged 36% of them. India houses 741 Drug manufacturing facilities registered with USFDA. Following are Top Ten formulation exporting countries

Top Ten formulation exporting Countries $ Mn						
Rank	**Country**	**2017**	**2018**	**2019**	**Change%**	**Cont bn%**
1	Germany	56961.31	65338.68	60111.28	1-8.00	13.91
2	Switzerland	42152.05	46136.43	48552.34	5.24	11.23
3	Belgium	34508.94	36229.25	40091.69	10.66	9.28
4	France, Monaco	28244.62	31178.96	33052.77	6.01	7.65
5	USA	27369.25	29194.60	31648.88	8.41	7.32
6	Ireland	24754.31	30868.20	26666.31	-13.61	6.17
7	Italy	20337.26	21303.39	26310.45	23.50	6.09
8	United Kingdom	27075.72	25260.68	23357.81	-7.53	5.40
9	Netherlands	16145.64	18408.62	20435.75	11.01	4.73
10	India	12773.85	14116.80	15966.50	13.10	3.69
	World	**387759.50**	**420164.53**	**432157.05**	**2.85**	**100.00**

Source: Uncomtrade

The analysis of the FDA warning letters of the last 10 years (January 2010 to Dec 2021) issued to Indian pharmaceutical industries is undertaken for evaluation to see the economical impact. The details of warning letters pertaining to Indian pharmaceutical industries are summarized in below Table 3.

Table 3. Summary of Warning letters issued by US FDA to Indian Pharmaceutical Industry

Sr. No.	FEI Number	Firm Name	WLs Date	Case/Injunction ID
	3015394334	Biotek India	05/13/2021	613295
	3009876430	Shilpa Medicare Limited	10/09/2020	607877
	3007187282	Panacea Biotec Pharma Limited	09/25/2020	607837
	3010910756	Mayon'S Pharmaceuticals Pvt Ltd	09/04/2020	607388
	3003227156	Mylan Laboratories Ltd. (Unit 7)	08/20/2020	607508
	3003821988	Wintac Limited	08/13/2020	606700
	3016998483	Kegan Wellness	07/13/2020	608737
	3015658387	Vega Life Sciences	06/17/2020	604469
	3011108348	Dr. Dhole's Sushanti Homeopathy Clinic	05/04/2020	607348
	3009167769	Kumar Organic Products Limited	04/23/2020	598683
	3002808145	Shriram Institute for Industrial Research	04/15/2020	597629
12	3016551424	Alpha Arogya India Pvt. Ltd. (The	04/13/2020	606253

Sr. No.	FEI Number	Firm Name	WLs Date	Case/Injunction ID
		GBS Group)		
13	3016601904	Homeomart Indibuy	04/01/2020	605888
14	3008316085	Pfizer Healthcare India Private Limited	03/24/2020	594972
15	3005339091	Windlas Healthcare Private Limited	03/10/2020	595494
16	3014466792	ESSND GLOBAL	02/14/2020	595850
17	3009223273	JHS Svendgaard Hygiene Products Ltd	02/13/2020	593473
18	3004081307	Cipla Limited	02/12/2020	597511
19	3008311641	Gpt Pharmaceuticals Private Ltd	12/17/2019	590938
20	3002785310	Mylan Laboratories Limited (Unit 8)	11/05/2019	589297
21	3002984011	Cadila Healthcare Limited	10/29/2019	584856
22	3005029956	Torrent Pharmaceuticals Limited	10/08/2019	585255
23	3005757050	Glenmark Pharmaceuticals Limited	10/03/2019	582701
24	3002807511	Lupin Limited	09/10/2019	572345
25	3012390454	Lantech Pharmaceuticals Limited	08/08/2019	580027
26	3005151215	Emcure Pharmaceuticals Limited	08/02/2019	576961
27	3006254924	CTX Lifesciences Private Ltd.	07/12/2019	577416
28	3006644152	Indoco Remedies Limited (Plant I)	07/09/2019	575313
29	3012448465	Strides Pharma Science Limited	07/01/2019	576722
30	3004611182	Aurobindo Pharma Limited	06/20/2019	577033
31	3005269310	Rxhomeo Private Limited	06/13/2019	575889
32	3009729392	Glint Cosmetics Pvt Ltd	05/31/2019	573468
33	3008342939	Centurion Laboratories Private Limited	05/04/2019	571255
34	3006217304	Contacare Ophthalmics & Diagnostics	04/23/2019	570360
35	3010212308	B. JAIN PHARMACEUTICALS PRIVATE LIMITED	03/21/2019	567957
36	3006895982	Jubilant Generics Limited	03/06/2019	569799
37	3008386908	Pfizer Healthcare India Private Ltd.	03/04/2019	557890
38	3007450508	Anicare Pharmaceuticals Pvt Ltd.	02/28/2019	569251

Sr. No.	FEI Number	Firm Name	WLs Date	Case/Injunction ID
39	3003090962	Vipor Chemicals Private Ltd.	01/29/2019	555392
40	3003658163	Skylark CMC Private Limited	12/03/2018	567229
41	3004974700	Wilson Medicine Company	09/11/2018	557206
42	3006076314	Apotex Research Private Limited	08/09/2018	547439
43	3005543404	P Banerji Mihijam Pharmaceuticals	08/07/2018	547958
44	3011783104	JT Cosmetics & Chemicals Pvt Ltd.	07/27/2018	554478
45	3004610460	Baxter Pharmaceuticals India Pvt Ltd	07/05/2018	543187
46	3011543431	Reine Lifescience	05/09/2018	548293
47	3009336980	Goran Pharma Pvt Ltd	04/24/2018	545331
48	3003677831	Keshava Organics Pvt. Ltd.	03/15/2018	540146
49	3005115135	Malladi Drugs & Pharmaceuticals Ltd.	03/09/2018	541915
50	3005216842	Alchymars ICM SM Private Limited	02/16/2018	542879
51	3007931994	Fleming Laboratories Limited	02/14/2018	537647
52	3006210232	Fresenius Kabi Oncology Limited (Baddi)	12/18/2017	526863
53	3003519498	Fresenius Kabi Oncology Ltd	12/04/2017	538641
54	3004819820	Lupin Limited	11/06/2017	532465
55	3007549629	Lupin Limited	11/06/2017	535014
56	3006370331	Kim Chemicals Private Ltd.	10/16/2017	535531
57	3007474872	Vital Laboratories Pvt Ltd Plant II	10/11/2017	527253
58	3008307735	Hetero Labs Limited (Unit V)	08/15/2017	520359
59	3003978209	Vista Pharmaceuticals Limited	07/05/2017	515652
60	3004982352	Vikshara Trading & Investment Ltd.	04/28/2017	516856
61	3003916387	Sal Pharma	04/20/2017	516205
62	3004149463	Divi's Laboratories Ltd. (Unit II)	04/13/2017	518434
63	3005124189	Indoco Remedies Limited	03/31/2017	514601
64	3005587313	Mylan Laboratories Limited	03/31/2017	517906
65	3004086192	USV Limited	03/10/2017	510159
66	3004058356	Badrivishal Chemicals & Pharmaceuticals	03/06/2017	511820

Sr. No.	FEI Number	Firm Name	WLs Date	Case/Injunction ID
67	3006688078	Megafine Pharma (P) Limited	02/24/2017	510862
68	3004483648	Resonance Laboratories Private Limited	02/03/2017	511907
69	3006254924	CTX Lifesciences Private Ltd.	01/18/2017	496393
70	3002808500	Wockhardt, Ltd.	12/23/2016	495920
71	3005048741	Srikem Laboratories Pvt. Ltd.	11/10/2016	496015
72	3010532174	Pan Drugs Limited	08/25/2016	490052
73	3004414652	Unimark Remedies Limited	08/12/2016	483816
74	3008117347	Unimark Remedies Limited	08/12/2016	483816
75	3007931994	Fleming Laboratories Limited	06/21/2016	438607
76	3012278106	Anil Gangwani	06/02/2016	495560
77	3005694111	Megafine Pharma (P) Limited	05/19/2016	479195
78	3007287078	Polydrug Laboratories Pvt. Ltd.	04/14/2016	477491
79	3005280525	Sri Krishna Pharmaceuticals Ltd. - Unit II	04/01/2016	472869
80	3005151215	Emcure Pharmaceuticals Limited	03/03/2016	455201
81	3002807297	Ipca Laboratories Limited	01/29/2016	442963
82	3005977675	Ipca Laboratories Limited	01/29/2016	442963
83	3007574780	Ipca Laboratories LTd	01/29/2016	442963
84	3002984011	Cadila Healthcare Limited	12/23/2015	471062
85	3006595385	Cadila Healthcare Limited (Zyfine)	12/23/2015	471062
86	3002809586	Sun Pharmaceutical Industries Ltd.	12/17/2015	458804
87	3005447965	Dr. Reddy's Laboratories Limited	11/05/2015	481160
88	3002949085	Dr. Reddy's Laboratories Limited CTO VI	11/05/2015	481160
89	3006549835	Dr. Reddy's Laboratories Ltd.	11/05/2015	481160
90	3003737804	Sandoz Private Limited	11/02/2015	445532
91	3004944629	Sandoz Private Limited	11/02/2015	445532
92	3005202703	Unimark Remedies Ltd.	09/29/2015	429340
93	3003263118	Pan Drugs Ltd.	09/02/2015	446630
94	3007512701	Mylan Laboratories Limited	08/07/2015	464863
95	3003813519	Mylan Laboratories Limited (Sterile Products Division)	08/07/2015	464863
96	3007648351	Mylan Laboratories Limited, Speciality Formulation Facility	08/07/2015	464863

Sr. No.	FEI Number	Firm Name	WLs Date	Case/Injunction ID
97	3004544153	Sipra Labs Limited	07/23/2015	431553
98	3003802404	Mahendra Chemicals	07/13/2015	438517
99	3005925733	Sharon Bio-Medicine Limited	06/22/2015	471663
100	3003978209	Vista Pharmaceuticals Limited	06/22/2015	471701
101	3006076314	Apotex Research Private Limited	01/30/2015	437669
102	3005210225	Micro Labs Limited	01/09/2015	437438
103	3004161432	Sharp Global Limited	10/15/2014	428474
104	3002806711	Cadila Pharmaceuticals Limited	10/15/2014	429369
105	3006257565	Amanta Healthcare Ltd.	08/26/2014	438593
106	3006257565	Amanta Healthcare Ltd.	07/08/2014	418268
107	3005466325	Apotex Pharmachem India Pvt Ltd.	06/16/2014	423752
108	3005409363	Sun Pharmaceutical Industries Limited - Karkhadi	05/09/2014	418746
109	3004896392	Smruthi Organics Limited	03/06/2014	416931
110	3003297374	Canton Laboratories Pvt. Ltd.	02/27/2014	413940
111	3003255171	Usv Limited	02/06/2014	413332
112	3002808503	Wockhardt Limited	11/25/2013	412858
113	3007648351	Mylan Laboratories Limited, Speciality Formulation Facility	09/09/2013	409756
114	3008250236	Sentiss Pharma Pvt. Ltd.	08/12/2013	398060
115	3006418686	Aarti Drugs Limited	08/02/2013	397189
116	3009688205	Aarti Drugs Ltd	08/02/2013	397189
117	3001329340	Posh Chemicals Private Limited	08/02/2013	398629
118	3005289335	Wockhardt Limited	07/18/2013	396819
119	3007972864	AMRUTAM LIFE CARE PRIVATE LIMITED	07/15/2013	395196
120	3003519498	Fresenius Kabi Oncology Ltd	07/01/2013	393890
121	3008386908	Pfizer Healthcare India Private Ltd.	05/28/2013	382438
122	3003269328	RPG Life Sciences Limited	05/28/2013	392574
123	3008314161	RPG Life Sciences Limited	05/28/2013	392574
124	3010004588	Discount Online Pharmacy	02/12/2013	392439
125	3009966662	buy-pharma.com	02/04/2013	391562
126	3003916387	Sal Pharma	05/30/2012	301698
127	3003263118	Pan Drugs Ltd.	02/28/2012	284758

Sr. No.	FEI Number	Firm Name	WLs Date	Case/Injunction ID
128	3003821988	Wintac Limited	02/23/2012	241074
129	3003747592	Xylo Chem Industries	11/16/2011	218896
130	3004896339	Yag Mag Labs Private Limited	09/12/2011	213033
131	3002984011	Cadila Healthcare Limited	06/21/2011	192132
132	3004021263	Aurobindo Pharma Limited, Unit VI	05/20/2011	180094
133	3008494993	Synbiotics Limited	12/16/2010	136712
134	3004610460	Baxter Pharmaceuticals India Pvt Ltd	11/01/2010	134950
135	3008299032	Choksi Laboratory	09/30/2010	135190
136	3004983128	Stericon Pharma Pvt. Ltd.	08/24/2010	122649
137	3008186667	Shreeji Homeo Clinic	04/13/2010	95710

Source:https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters

Exports of pharmaceutical products from Indian region to USA for the period of 2010-20 was evaluated as case study.

[Fiscal Year]	**Warning Letters-Global**	**WLs Count-(India)**	**India's exports to United States of America**
2010	669	2	1,656
2011	1738	3	1,543
2012	4891	2	2,417
2013	6766	8	11,155
2014	8800	4	44,684
2015	17238	11	68,251
2016	14586	8	97,641
2017	15326	9	98,059
2018	14483	4	98535
2019	15099	15	87154
2020	5512	8	101454
2021	294	2	Data not yet available

Total	105402	75	

Unit: US Dollar thousand, Source: ITC Geneva; Exim Bank Analysis

From the above data, it can be concluded that although there are WLs cases in India for the period of 2018-2020, in spite of this there is no impact on the exports ultimately the economical growth. This might be due to the exports was happened from the other pharmaceuticals where the WLs not imparted.

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