

In 5 yrs, US FDA rejected 13,000 Indian products

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Bengaluru: As many as 13,334 products made in India were rejected by the US Food and Drug Administration (FDA) between 2010 and 2015, FDA data shows. During the period, it rejected imports of 15,087 Chinese products.

According to the ministry of commerce and industry, the rejected products include patent medicines, generic medicines, snacks, bakery products, spices (ground, mixed) and seasonings, bath soaps and detergents. And, the reasons include problems in packaging, misbranding, contamination, high residue levels and labelling.

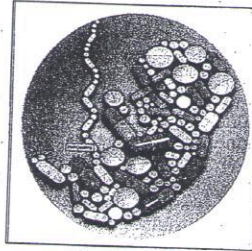
In January 2016, India saw 228 rejections — China saw 314 — pointing to another year of huge rejections at a time when the Centre has been advancing the 'Make-in-India' campaign. On January 5, 2016, three drugs from Intas Pharmaceutical Limited and Sanofi India Limited, were rejected as they were unapproved drugs under sections "505(a), 801(a)(3)" of the US regulator's guidelines.

When asked to comment about the rejections, Biocon CMD Kiran Mazumdar-Shaw said: "I cannot comment on specific cases. But, there is a problem, ranging from data integrity issues where some of our firms have been caught fudging data red-handed, to issues with clean environments — there was a case where a sterile area had a leaky roof — which is unacceptable and so on." Shaw added: "Just look at the warning letters issued to our firms, I won't name... but they are in detail. And not arbitrary."

On January 6, two items exported by Andhra Pradesh's RDR-Export were rejected by the US FDA citing adulteration. "The article appears to bear or contain a food additive, namely nitrofurans, that is unsafe," the FDA says regarding one of the items.

Experts say there have been several issues over the ye-

In January this year, India saw 228 rejections by the US food and drugs regulatory body, pointing to another year of huge rejections at a time when the Centre has been advancing the Make-in-India agenda. Rejected products include patent medicines, generic drugs, snacks, bakery products, spices and seasonings, soaps and detergents



ars and that it is not new to see such high rejection rates from the United States. However, the number of rejections was consistent, although not with huge differences, decreasing from 2012 to 2014. That changed in 2015, when 2,311 Indian products were rejected — slightly less than China's 2,461.

Speaking to TOI from Delhi, Ajay Sahai, director general & CEO of the Federation of Indian Export Organisation (Fieo), said: "Until a year ago, the Indian industry's focus was not on standard and quality. There may be a lot of reasons for this, but if one has to compete in the global market, this has to be adhered to."

He said there is a need for standardisation of quality in the country and that the Centre must take this up on a war footing. "The ministry of commerce has some initiatives and several 'standard conclaves' have been conducted. But that is not enough. We are late to start, so we need to do a little more," he said.

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