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

Chethan Kumar
@timesgroup.com

Bengaluru: As many as 13,394 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 2015, 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 India, Sanofi and Sandoz, were rejected as they were unapproved drugs under sections "505(a)(3)(B)(v)" of the US regulator's guidelines.

When asked to comment about the rejections, Micron CMD Kran Murugesh 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 5, two items exported by Andhra Pradesh's RRB 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 years and that it is not new to see such high rejection rates from the US FDA. However, the number of rejections was consistent, although not with huge differences, decreasing from 2012 to 2014. That changed in 2015, when 231 Indian products were rejected — slightly less than China's 246.

Speaking to TOI from Delhi, Ajay Sahai, director general & CEO of the Federation of Indian Export Organisations (FIEO), said: "Until a year ago, the Indian industry's focus was not on standard and quantity. 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 regulations have been conducted. But that is not enough. We are late to start, so we need to do a little more," he said.