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Sanofi files first-of-a-kind suit against FDA

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Singapore: Sanofi has filed a lawsuit against the US FDA in hopes of preventing the regulatory agency from releasing packaging information of its newly approved over-the-counter (OTC) allergy spray, Nasacort. Sanofi claimed that the spray is proprietary and releasing the 'labeling' information will spill trade secrets. The US FDA has, so far, not responded in court.

Since, the US FDA is required to publish approval information on its web site, the move appears to be a first-of-its-kind lawsuit. Sanofi has been arguing with the FDA over publication of the information and filed the suit only after it was informed that the info would become publicly available on November 12, 2013.

Sanofi claimed that four requests for the labeling and production information have been filed under the Freedom of Information with the US FDA. In arguing its case, Sanofi said that the labeling and packaging material is actually confidential and commercial information, which would make this exempt from disclosure under what is known as Exemption 4 of the Freedom of Information Act.

Sanofi was not granted marketing exclusivity for its OTC Nasacort spray, and argued that releasing information before its Chattem unit launches the product next year, could give competitors an edge.

Without marketing exclusivity, generic rivals will be able to launch competing medicines and release of any labeling information will help them to make another version of Nasacort 24 Hour spray. In approving the OTC version, the FDA followed the recommendation of an advisory panel to do away with prescriptions for the 24 Hour spray for seasonal and year-round allergies.