US warned French implant maker as far back as 2000

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The US Food and Drug Administration warned a French maker of breast implants now feared to be at risk of rupture of "serious" quality control violations involving saline implants back in 2000.

Following a May 2000 inspection of a factory in France operated by Poly Implant Prothese (PIP), the FDA sent a firm warning letter dated June 22, 2000, warning saline implants made at that facility were "adulterated."

The letter, seen by AFP, outlines a list of quality assurance problems the FDA warned "may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems."

The company is currently under scrutiny not for its saline implants, but for its silicone implants. PIP is suspected of fraudulently using a poor-quality gel for those devices which is linked to leakage and inflammation problems.

France's health ministry has advised 30,000 women in France with PIP silicone breast implants to have them removed, saying that while there is no proven cancer risk, the prostheses could rupture.

Prosecutors in Marseille, near PIP's home base of La-Seyne-sur-Mer, have received more than 2,000 complaints from Frenchwomen who received the silicone implants, and have opened a criminal investigation into the firm.

Documents obtained by AFP showed tens of thousands of women in more than 65 countries, mainly in South America and western Europe, received silicone implants produced by PIP.

An FDA spokeswoman said Tuesday she could not confirm if the results of the May 2000 inspection were also relayed to French health authorities.

"Our warning letter was publicly available in 2000. Given the timeframe, I haven't been able to confirm whether any information was shared with France," said the spokeswoman, Erica Jefferson.

But "generally speaking, when the FDA conducts inspections in foreign countries of foreign facilities, they are aware of our presence in country," she added.