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Ranbaxy asked to review units catering to US

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THE US drugs regulator has asked Indian pharma company Ranbaxy to immediately assess the manufacturing practices at its plants that make drugs for the American market, saying the company has failed to adequately address the concerns raised by it earlier. FDA expects Ranbaxy to immediately undertake a comprehensive assessment of its global manufacturing operations to ensure that all sites manufacturing drug for the US market conform to US requirements, the US Food and Drugs Administration (FDA) said this while issuing a warning letter for one of its plants in the US recently.

The warning will not have any immediate financial impact on the company, majority-owned by Japanese pharma company Daiichi Sankyo, as it does not mean a ban on the drugs made at the plant. The US market accounted for about a quarter of Ranbaxys \$1.6 billion revenues for the year ended 2008. It is not known how many FDA-approved facilities the company has globally. But in the US alone, it has at least three such plants, two of which were cleared by the FDA during a recent inspection while one got the warning letter.

The Gurgaon-based firm said it has nothing to add beyond the statement it issued on December 24 at the time of receiving the warning letter from the FDA. The warning letter was posted on the FDA website on Wednesday.

Ohm Laboratories, Ranbaxys US subsidiary, received the warning letter on December 21, 2009, from the FDA for its liquid manufacturing facility located in Gloversville for violations of US manufacturing standards during inspections between July and August 2009. Since then, Ohm has hired the services of PRTM, a global consulting firm, to provide expertise and advice on issues raised by the FDA.

Earlier this year, the FDA had inspected two other plants of Ohm and did not observe any material deviation. These plants manufacture most of the products supplied in the US market, Ranbaxy had said. FDA said the violations noted at Gloversville are similar to those deviations pointed out by the regulator to the company in June 2006 at its Poanta Sahib plant in Himachal Pradesh and later in September 2008 at plants in Dewas, Madhya Pradesh and Poanta Sahib. Though it is facing problems with the US regulator, Ranbaxy has got multi-year approvals from regulators of several European countries, Japan and Australia for the two Indian plants under the FDAs scanner. Ranbaxy has been co-operating with the FDA and is awaiting a reinspection of its Dewas plant. It has also sought the American regulators nod to start selling drugs from a new plant in India. Independent regulatory experts say the FDA move could just be a warning, though it is unusual and unfair to link the Glouversville plant with the two Indian plants whose drugs are banned in the United States. In the case of the US one, it is a mere warning letter, said an industry veteran. Hemant Bakhru, pharma analyst with brokerage firm CLSA, said this could mean stricter scrutiny for Ranbaxy when the FDA inspects its plants in India and abroad.