

Bristol-Myers Warned Of Subpar Practices In Puerto Rico

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SAN JUAN, Puerto Rico (AP) — The U.S. Food and Drug Administration has warned drug giant Bristol-Myers Squibb Co. of possible sanctions if it fails to correct "significant violations" of good manufacturing practices at one of its two plants in Puerto Rico.

The drugmaker said it has already begun correcting problems mentioned in the warning letter that the U.S. agency posted on its website Tuesday.

Regulators said the New York drugmaker's plant in the northern coastal town of Manati has not established or followed rules to prevent contamination of drugs. The observation followed an inspection in March, and federal officials found similar cleanliness problems in 2005 and 2009.

Regulators also said the company has failed to investigate subpar manufacturing practices and standards, and that there have been ongoing problems with employees complying with procedures implemented due to these recurrent violations.

The Manati plant manufactures the brand-name drug Orencia, for rheumatoid arthritis; and the brand-name anti-clotting drug Coumadin, among others. It is one of 14 manufacturing plants worldwide, and a company spokeswoman said she did not have a specific breakdown of what percentage of the company's total output is produced at the Puerto Rico plant.

"Your firm has not established scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality, and purity," the FDA's letter said.

Bristol-Myers spokeswoman Sonia Choi said the company takes the warning very seriously and is working with the FDA to address the problems at the plant.

"We have already initiated a number of corrective steps in response to the observations, including engaging a third-party consultant to assess our facility, procedures, processes and systems," Choi said in an e-mail.

The FDA said the company's initial response to regulators in April lacked sufficient corrective actions. Regulators could withhold approval of pending drug applications if the violations are not fixed.

Bristol-Myers is one of the world's largest drugmakers. Among the medicines it

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manufactures is Plavix, a blood thinner that is the world's second-best-selling brand name drug. Its other products include the psychiatric disorder treatment Abilify; HIV drugs Reyataz and Sustiva; and Onglyza for diabetes. None of these drugs is manufactured at the Puerto Rico plant.

In 2006, the company announced a \$200 million expansion of the Manati plant, which included adding 100,000 square feet (9,290 square meters) to allow for the packing of sterile products and the production of biologic drugs, such as Orencia, which are made from a living organism or its products.

The U.S. Caribbean island has long had one of the world's highest concentrations of drugmakers, but in recent years companies have shed thousands of jobs and closed several plants for a variety of reasons, including the loss of federal tax breaks and cost-cutting.

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