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# Some Of The Drospirenone (DRSP) Progestin Used In Yaz And Yasmin Pills May Have Been Of Bad Quality

## August 2009 FDA Warning Letter Sent To Bayer Relates To Quality Control Problems Found In March 2009 At German Facility Where DRSP Was Made

(Posted by Tom Lamb at www.DrugInjuryWatch.com on September 16, 2009; see http://bit.ly/iEgvw)

By means of a September 15, 2009 *Associated Press* (*AP*) news article, "FDA Warns Bayer Over German Manufacturing Plant", we first learned about a Warning Letter sent by the FDA back on August 5, 2009.

The *AP* article suggests that this Warning Letter sent to Bayer by the FDA in early August 2009 was not made public until mid-September:

> In a warning letter posted online [September 15, 2009], the Food and Drug Administration said its inspectors uncovered testing problems at [Bayer's] plant in Berghamen, Germany, during a March visit.
>
> FDA inspectors said the company measured the quality of its drug ingredients based on an average of several samples, instead of reporting individual tests results.
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> Bayer shipped eight drug batches to the U.S. that were tested using the method, which the FDA does not accept.
>
> The drug ingredients included drospirenone, which is used in the popular birth control pills Yaz and Yasmin. Those products were the company's top-selling pharmaceuticals last year, with global sales of $1.8 billion.

In this August 5, 2009 FDA Warning Letter to Bayer, the agency told the drug company that about eight batches of ingredients used in the drugs Yaz, Yasmin, and Angeliq "should not have been released for distribution".

Yaz and Yasmin are combined oral contraceptive (COC) pills that contain ethinylestradiol (EE) and the new "fourth generation" progestin drospirenone (DRSP). Yaz and Yasmin have been linked to blood clots and cardiovascular events as well as other serious side effects. Some medical researchers have offered the theory that it is the DRSP component in Yaz and Yasmin that might cause some of these adverse reactions.

Angeliq tablets (drospirenone/estradiol) are used as hormone therapy (HT) to relieve moderate to severe menopausal symptoms such as hot flashes and night sweats.

In more detail, this August 2009 Warning Letter was sent by FDA's Richard L. Friedman, M.S. -- the Director of the agency's Division of Manufacturing and Product Quality, Office of Compliance, Center for Drug Evaluation and Research -- to Bayer's Dr. Franz-Josef Renneke -- who is the Site Manager for Bayer HealthCare - Bayer Schering Pharma AG at its manufacturing facility in Bergkamen, Germany. The Warning Letter concerns certain batches of drospirenone (DRSP), ethinylestradiol (EE), and norethisterone acetate that were manufactured at this particular Bayer facility in Germany.

A response from Bayer about points raised in the FDA Warning Letter was due within thirty days of August 5, 2009, according to the letter. To our knowledge, however, neither Bayer nor the FDA has made any such response letter publicly available as of September 16, 2009.

We will report any future significant developments about the apparent quality control problem involving drospirenone to the extent that they call into question the safety of Yaz, Yasmin, and Angeliq.

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Attorney Tom Lamb represents people in personal injury and wrongful death cases involving unsafe prescription drugs or medication errors. The above article was posted originally on his blog, **Drug Injury Watch** – with live links and readers' Comments.
http://www.DrugInjuryWatch.com