

HOGAN & HARTSON  
L.L.P.

COLUMBIA SQUARE  
555 THIRTEENTH STREET, NW  
WASHINGTON, DC 20004-1109  
TEL (202) 637-5600  
FAX (202) 637-5910  
WWW.HHLAW.COM

December 2, 2004

*BY HAND DELIVERY*

Division of Dockets Management, HFA-305  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, Maryland 20852

**Re: Submission to Citizen Petition, Docket No. 2004P-0523**

Dear Sir or Madam:

On November 23, 2004, we submitted a citizen petition on behalf of GlaxoSmithKline ("GSK"). See Docket No. 2004P-0523. In that petition, we referred to an article published in FDA Week on November 5, 2004, *Generics May Get Leeway on Some Strict Manufacturing Specifications*. We also stated that an authorized copy of the article would be submitted as soon as possible; it is attached. Please include it behind Tab C of our petition.

Sincerely,



Brian R. McCormick  
Hogan & Hartson L.L.P.

Enclosure

2004P-0523

SUP 1

## GENERICS MAY GET LEEWAY ON SOME STRICT MANUFACTURING SPECIFICATIONS

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**Date: November 5, 2004**

FDA is looking into ways for generic drug firms to avoid meeting strict manufacturing specifications set by brand-name companies that do little to make drugs safer, according to a top FDA official. By the time generic firms are copying drugs, advances in technology and improved understanding of the manufacturing process may make certain specifications unnecessary, according to another FDA source.

“We have some questions as to the relevance of some of these specifications that are set by the innovator industry and we find ourselves often in these situations where we’re held to these really tight specifications that are really hard to meet and probably have really no scientific underpinnings,” said Helen Winkle, FDA director of the office of pharmaceutical sciences.

Winkle spoke at the Generic Pharmaceutical Association Friday (Oct. 29). She said FDA is holding a “specifications workshop” in March. She urged the generic drug industry needs to make sure their representatives participate in the forum because the advisory group will likely make important recommendations.

“I think this is one of the more important things we’re going to do next year is focus more on specifications setting and how best to do that,” Winkle said. “I think the agenda and the break out sessions we’re planning for are really quite good and [include] all issues that we should have address a while back.”

Winkle said FDA will examine the role that both the U.S. Pharmacopeia and industry play in setting specifications and how they affect the manufacturing of generic drugs.

FDA officials have been devoting much of their time to revamping the way the agency regulates drug manufacturing. The good manufacturing practices (GMP) initiative, led by Associate Commissioner Janet Woodcock, has focused much more on the innovator industry, but Winkle insists that it will affect the generic drug industry too.

“We [Office of Pharmaceutical Science] need to work with the generic industry to better understand their processes to help improve on their efficiency and to ensure an understanding with the industry on what PAT [process analytical technology] can mean for them,” she said.

FDA is revising many of its GMP rules and guidances, and Winkle emphasized that the generic industry must make sure they understand how those changes will affect companies.

“If there is something that is causing pain to your industry we need to know that as well,” she said.

FDA’s work on the process analytical technology is one of the main parts of the GMP initiative. PAT focuses on a systems perspective and the role of new technology in manufacturing.

Ajaz Hussain, deputy director of the pharmaceutical science office, said Wednesday that the generic drug industry is having a difficult time understanding what PAT is. He said FDA’s pharmaceutical science advisory committee will form a work group tasked with outlining concrete examples of how companies can use PAT to upgrade their manufacturing facilities, which could lead to less FDA regulation (see FDA Week, Oct. 29).

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