



November 30, 2004

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fisher Lane, Room 1061
Rockville, MD 20752

Re: White Paper entitled "Risk-Based Method for Prioritizing CGMP Inspections of Pharmaceutical Manufacturing Sites—A Pilot Risk Ranking Model"

Pfizer thanks FDA for their time and effort in developing this model and sharing it with the general public. Pfizer supports the concept of the Agency applying a risk-based model as a way of setting inspectional priorities and deploying resources. Risk-based models are well recognized as appropriate decision-making tools in a broad range of industries. Pfizer supports the use of risk management principles in the pharmaceutical industry.

Point 1: Volume & Complexity of Product Mix

The Agency states some processes are more complex and more susceptible to problems than others. They have indicated high volume processes may be identified as "high risk".

The complexity of the product mix is a more critical risk factor than production volume by itself. The complexity of the product mix and how it is controlled at a given site should be added as a factor which impacts risk.

High production volume is not necessarily an indicator of potential for risk. Often production processes for high volume products are highly reliable and have been fine-tuned over time to provide high process capabilities. Contrarily, low volume products manufactured only a few times a year can sometimes have lower process capabilities due to less frequent opportunities to reduce variability.

Point 2: Improved Data Acquisition

FDA indicates they will adjust and redesign the model using expert assessment and peer review. They will also seek opportunities for source data outside the Agency, including a survey of existing practices or elicitations of industry experts.

There are many industry groups eager to collaborate with the Agency on various topics. Pfizer suggests the Agency use these independent groups to augment the data thus improving this risk based model for inspections.

2003N-0059

C7



Point 3: Transparency

The FDA does not plan to make the actual risk assessment process elements available to industry. This lack of transparency in the process is problematic for those sites needing the information to improve their quality systems. The knowledge of those risk factors can be a valuable input into a site's quality planning process as discussed in the Draft Guidance for Quality Systems.

There will be no apparent means to correct misconceptions about products, processes and facilities that may result in a particular site being characterized as "riskier" and a high priority for inspection. Inability to correct such miscalculations could result in inefficient use of the Agency's inspectional resources; the direct opposite of the intent of the pilot program. It is reasonable to expect many companies in the industry would wish to perform a risk analysis of their own sites, using the same model as the Agency, to define its quality systems and create a meaningful quality plan.

Point 4: Use of Risk Management

In the document, FDA has stated sites successfully implementing risk mitigation techniques would likely have a better inspectional history and fewer recalls. While Pfizer accepts this as true, we feel the Agency should acknowledge there could be differences between the firm and the agency with respect to the application of risk management. This supports the need for the ICH Guidance (ICH Q9) on Quality Risk Management.

Point 5: Linkage of the White Paper to other Aspects of the FDA Initiative

The Agency has stated in the document, an assurance the depth of inspections is similar for all high risk sites. Since the depth and quality of the inspections are based upon the individual field investigators, the training of the pharmaceutical inspectorate is an important function to assuring consistency, especially for high risk sites. The curriculum for the inspectorate should include both the approach for inspecting high risk sites as well as risk management principles.

Sincerely,

A handwritten signature in cursive script that reads "Zena Kaufman".

Zena G. Kaufman
Pfizer Global Manufacturing
Sr. Director Regulatory Compliance Initiatives