



Genzyme Corporation  
500 Kendall Street  
Cambridge, MA 02142  
T 617-252-7500

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

**Subject: Docket No. 2006N-0183  
Agency Information Collection Activities; Proposed Collection; Comment  
Request; Guidance on Reagents for Detection of Specific Novel Influenza A  
Viruses**

21 July 2006

Dear Sir/Madam:

Thank you for the opportunity to comment on the notice entitled "**Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance on Reagents for Detection of Specific Novel Influenza A Viruses**" issued 22 May 2006. This guidance recommends that sponsors obtain and analyze postmarket data to ensure the continued reliability of their device in detecting the specific novel influenza A virus that it is intended to detect, particularly given the propensity for influenza viruses to mutate and the potential for changes in disease prevalence over time.

FDA estimates each respondent will spend 20 hours annually obtaining and analyzing the postmarket data, at a cost of \$350. FDA estimates 10 respondents, at a total cost to industry of \$3500.

Genzyme has a rapid test for influenza on the market, intended for use in hospital and physicians' offices. We have several rapid tests for infectious diseases available and are experienced in communicating with users of these devices. In addition, as required by QSR, we have an efficient system for notifications in the event of a field correction and can speak knowledgably about the cost of such notices and corrections. Based on this experience, we offer the following comments.

We believe the potential impact of the request could result in a serious underestimation of the burden of time and resources.

We believe the tasks of adequate vigilance and analysis of reports of outbreaks of "novel" strains being reported per year will easily amount to more than twenty hours.

For QSR/document control, we estimate the number of hours per change at 15, rather than FDA's estimated 10. In addition, if labeling is to be updated, the amount of time that the sponsor has to

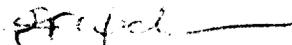
update the labeling would affect the increase in time allotted to the activity. The sponsor also would need to determine if the risk of the virus penetrating the markets that it serves would need to be assessed. It is unclear if the sponsor is responsible for World Wide information for the outbreak, if the device is available in all or some regions. If so, translations would add additional costs and time commitments, with an estimate of 3 hours per language for certified translation.

The status of "old" labeling that does not contain the update is unclear. Would the "old" labeling deem the product "misbranded" and subject to all products in distribution to recall or field correction?

If a recall or field correction is necessary, there will also be compliance risks (depending on FDA's interpretation of the requirement), resulting in significant costs of end-user contact and confirmation. For a highly distributed product, this could amount to \$20,000 to \$50,000 in time and resources.

Genzyme appreciates the opportunity to comment on this notice. Please contact me at 617-768-6275 or Linda Temple at 617-768-9290 should you have any questions regarding this letter.

Cordially,



Robert E. Yocher, RAC  
Vice President, Regulatory Affairs and  
Corporate Quality Compliance  
Genzyme Corporation