



Customhouse Brokers

305 Harbor Way, South San Francisco, CA 94080 TEL: (650) 794-1388 FAX: (650) 794-1389

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MAY 7, 2004

Food & Drug Administration
Division of Dockets Management (HFA-305)
5630 Fishers Lane Rm# 1061
Rockville, MD 20852

"The Prior Notice requirements of the Bioterrorism Act are not working on the FDA side nor on the side of filers nationwide. FDA is currently unable to notify filers when there are data errors that will result in penalties once FDA begins implementation of Phase Four on August 14, 2004. The lack of information available to filers regarding the nature and scope of errors does not bode well for the flow of legitimate trade in the near future. According to FDA records, over 50% of current Prior Notice transmissions are inaccurate or inadequate.

"Because the system is clearly not working, we request that Phase Four implementation scheduled for August 13, 2004, be moved back at least 6 months to enable both FDA and entry filers to receive proper training.

"The Act was made into law to protect our food supply. As it stands now, it will not protect our food supply but will surely result in the refusal of a large amount of legitimate importations and in the unfair assessment of penalties against law abiding importers and entry filers.

"We request that Phase Four implementation of FDA Prior Notice requirement be postponed for six months."

Respectfully,

Bob Kirk
EWI inc. CHB

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