

FDA Computer System Down for Emergency Maintenance

The U.S. Food and Drug Administration (FDA) sent notification this afternoon that due to unplanned emergency system maintenance, both the FDA OASIS and Prior Notice System Interface (PNSI) will be down from 3:30 p.m. EST today until 6:00 a.m. EST on Tuesday, April 8, 2008. FDA has indicated that further information will follow as soon as it is available, and that status updates will be provided on the FDA website at <http://www.access.fda.gov/>.

This system downtime may affect the cargo release of shipments regulated by FDA.

The FDA notice was distributed via the U.S. Customs and Border Protection (CBP) Cargo Systems Messaging Service, and can be viewed online at: http://apps.cbp.gov/csms/csms.asp?srch_argv=08-000048&srctype=all&opt=1

CBP has provided the following information on how FDA Prior Notices will be processed during this system outage if submitted via ABI/ACS (NGJ Express, NGJ EDI) or PNSI. FDA will also accept prior notice submitted through their contingency website <http://vm.cfsan.fda.gov/~pn/pnsidown.html>, printed and faxed to the prior notice center.

1. Prior notice Submissions made via ABI/ACS

If Prior notice has already been submitted via ABI/ACS prior to the system outage and a Prior Notice Confirmation Number has been received, the submitter may proceed with Prior Notice USING THE STANDARD PROCESS. IF Prior notice was submitted and a confirmation number was not received prior to the outage, submitters should provide CBP officer, at time of cargo release a either an endorsed (signed) copy of the ABI transmission showing the PN submission or some other evidence adequate to show that a PN submission has been made via ABI/ACS.

2. Prior Notice Submission via PNSI

If prior notice has been submitted via PNSI, the confirmation number must accompany the article of food (21 CFR 1.279(g)). In addition FDA & CBP recommend that the submitter also provide the confirmation page including the prior notice confirmation numbers & time stamp, to CBP officers for cargo release. IF THE PNSI CONFIRMATION PAGE IS NOT PROVIDED THIS MAY DELAY CARGO RELEASE WHILE THE CBP OFFICER HAS TO CONTACT FDA FOR VERIFICATION.

PN CAN BE SUBMITTED VIA TO 703 261-8625

PN Center intends to Fax an acknowledgement report including PN confirmation number which can be presented to CBP for cargo Processing.

The Prior Notice center can be contacted at (866) 521-2297

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If you have questions, no longer wish to receive these notices via fax, or wish to receive these notices via e-mail, contact NGJ's Trade/Compliance Services Department at: compliance.us@ngjensen.com

Visit our website at www.ngjensen.com

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