
❖ SPC & B Update ❖

A Newsletter for Clients of Sharretts, Paley, Carter & Blauvelt, P.C.

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FDA TO IMPLEMENT NEW ITACS SYSTEM



The Food and Drug Administration (FDA) will, on March 14, 2012, provide public access to its new Import Trade Auxiliary Communications System (ITACS). ITACS is an Internet-based information system which will initially allow importers and their representatives to check the status of import entries subject to FDA clearance, electronically submit documentation relating to such entries, and provide shipment availability information to the FDA for goods that have been targeted for examination.

No login or account will be required to use the initial ITACS functions. However, in the future, the FDA plans to allow importers to access Notices of FDA Action through ITACS and add other functionality which will require a higher level of security in the form of account management.

To check the status of an entry, a user simply needs to input the entry number and the system responds with a brief description of the status of the merchandise (line-by-line if more than one entry line is involved). At the present time, only open entries may be queried, but the trade has requested, and the FDA is considering adding, the ability to query closed entries.

To submit documents on ITACS, a user inputs the entry number and then indicates whether he is submitting documents relating to the entire entry or to a specific entry line. He can then upload up to five PDF-formatted files per submission. ITACS requires the submitter to identify himself by name, firm name, and phone number. When documents are submitted through ITACS, FDA staff will see an icon on their computer screens to advise them of that fact.

Finally, to submit availability information, a user inputs the entry number and clicks a checkbox indicating the line of the entry to which the information pertains. There are three options for indicating the location of the goods: (1) Goods are available at the consignee address as filed; (2) Goods are

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available at the consignee address as filed, with additional optional information provided (such as contact name, contact phone number, warehouse/pier lot number, hours of operation, and other additional information); and (3) Provide updated information advising of a different location for the goods. Information identifying the submitter is required for all three options. For the third option, the facility name, the contact's name and phone number, and the facility's address must be provided, while other information, including warehouse/pier lot number, hours of operation, and other additional information, is optional.

As of March 14, ITACS may be accessed over the Internet at <https://itacs.fda.gov>. The FDA will have an email address for questions and support at itacssupport@fda.hhs.gov.

Anyone wishing additional information regarding the above should contact Gail Cumins at gcumins@spcblaw.com, Donna Shira at dshira@spcblaw.com, or Kenneth Paley at kpaley@spcblaw.com, or call us at 212-425-0055.
