

Summary of Meeting with Stuart Pape and
Joseph Whitmore of Formatta Corporation
April 11, 2003

ATTENDEES:

Joseph Whitmore, Formatta Corporation
Stuart Pape, Patton Boggs
Leslye Fraser, FDA
Melissa Scales, FDA
Irene Chan, FDA
Anne Taylor, FDA
Rosanne Kane, FDA
George Brush, FDA
Mary Ayling, FDA
Erwin Miller, FDA

Mr. Pape said the meeting was intended to introduce Formatta's software to FDA for use with registration and prior notice. He said the software was advantageous to both FDA and industry because it would assist FDA in collecting information pursuant to the requirements of the rules, while keeping the burdens on industry low. One of the advantages of the Formatta software is that it enables someone to fill out the form, then send it to others for updates before it goes to FDA. The application would be free for industry to use. Formatta sought to enter into a contract with FDA for use of the software.

During the meeting, Mr. Whitmore presented an electronic prior notice submission form that Formatta Corporation could produce for FDA. Several features of the electronic form were discussed, including:

- ?? Submitters may download the form from the website; put it on their own system; then when ready prepare it, sign it, encrypt it and submit it to FDA.
- ?? Form "wizard" features may be built into the form, along with help browser.
- ?? Form may have auto-fill, conditional tabbing and ability to disallow fields that are not correct.
- ?? Form may have electronic signature and date/time stamp features.
- ?? The registration number may hyperlink.
- ?? Drop down lists may be used for data elements such as states and ports.
- ?? Can be used as an automatic download such as Acrobat.
- ?? The form is 508 compliant.
- ?? In the event the FDA system is down, the product may be used to produce a paper form with a barcode containing all data on form that can be scanned to permit the data to be electronically imported into the prior notice system when it is available.