

## FDA REGULATORY APPLICATIONS OF FIELD PORTABLE EDXRF

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FDA has accumulated valuable experience employing field portable EDXRF to regulated products. These devices are currently in use at both FDA's Center for Food Safety and Applied Nutrition (CFSAN) and at the San Francisco District. They are a valuable asset for routine and non-routine elemental analysis investigations. In 2007, FDA's Division of Field Science sponsored a pilot study to explore the use of these analyzers in the field. Investigators from the San Francisco District were trained and certified in the use of these analyzers and used them to identify products containing abnormal levels of toxic elements. This pilot study demonstrated that investigators and non-chemists can use this equipment to quickly and accurately screen large numbers of FDA-regulated products. In the lab and for most samples, XRF will not substitute for techniques such as ICP-MS for sub-ppm level analyses. But XRF dramatically increases a lab's ability to triage and to investigate component of samples as well as the samples themselves. Significant advantages include minimal sample preparation, rapid and definitive identification of target elements, and semi-quantitative determinations of target elements at relatively low ppm levels.

This presentation will highlight the use of XRF for investigational and forensic-type applications of food and regulated products within the FDA, and illustrate how FDA can make better use of XRF results in the regulatory process in the future. At the present time, FDA has not established approved, validated XRF-based methods for specific target analytes and matrices. However, XRF results are used for sample triage both in the field and in the lab for identifying products that contain elevated levels of toxic elements as the basis for further investigation to trigger a regulatory action. Examples of products of interest include dietary supplements, Asian patent medicines, and some foods. Presently, we screen all dietary supplements via XRF before they enter our regular analytical process that is focused on low levels of toxic elements (which is most often based on microwave digestion followed by ICP-MS analysis). While XRF results alone have *not* been used as the *sole* means for regulatory decisions, they have provided convincing confirmatory evidence that is essential for the FDA regulatory process. In the future we plan to utilize XRF as a definitive regulatory tool where possible ( e.g. dietary supplements that contain percent levels of toxic elements).