Written Comments on Radio Frequency Identification (RFID) Technology submitted to the Federal Trade Commission (FTC) by the Food & Drug Administration (FDA)

ORIGINAL

Re: RFID – Workshop Comment, P049106

July 9, 2004

The FDA is pleased to submit these written comments as a supplement to the presentation we made on RFID at the FTC RFID Workshop on June 21, 2004.

The FDA's main interest in RFID is as a tool that has high potential to help keep the U. S. drug supply safe and secure. In the context of deterring and detecting the introduction of counterfeit drugs, we believe that RFID technology is the most promising approach for providing reliable tracking and tracing of drug products from the point of manufacture to the point of dispensing. We believe that the widespread use of RFID in the pharmaceutical supply chain, at the item level, is feasible by 2007.

We believe the deployment of RFID in the pharmaceutical supply chain will be driven by its many benefits that go well beyond the fight against counterfeit drugs. These benefits include:

- The ability to conduct fast, efficient, and targeted recalls;
- More efficient inventory management and control;
- Identification of diversion; and
- Improvement in patient safety by assuring correct dispensing of drugs.

However, there are a number of challenges that need to be addressed in order for widespread deployment of RFID to be accomplished at the item level. These include:

- Cost – tag cost must decrease in order for universal item level tagging to be feasible;
- Development of an RFID Infrastructure – in order to realize the full benefits of RFID, all entities in the drug supply chain must acquire the equipment, hardware, and software needed to integrate RFID into their other business systems, thereby enabling them to make maximal use of the data provided by RFID;
- Database Issues – the huge amount of information generated by RFID will need to be housed somewhere. Stakeholders will need to determine the most optimal database structure for managing this information (e.g., centralized, distributed). Optimal database structure may vary by industry. Additionally, security and access issues related to the database will also need to be addressed. These issues may also require industry specific solutions;

- Standards Development – there should be open, freely available technical and business standards for pharmaceutical industry use of RFID. Due to the global nature of the pharmaceutical industry, these standards should be global and should facilitate technological advancement as well as competition;
- Compliance with regulatory requirements – the pharmaceutical industry is highly regulated and its use of RFID must comply with applicable regulatory requirements (e.g., FDA requirements for labeling and current good manufacturing processes where applicable);
- Product Quality – data should be collected concerning the effect, if any, on product quality of the electromagnetic energy associated with the use of RFID;

With regard to these challenges, we recommend that the FTC take into account industry specific needs and issues as it determines what actions, if any, it wishes to take with regard to RFID technology.

In addition to the industry specific challenges mentioned above, use of RFID may raise certain labeling (e.g., if RFID is used to transmit health care information to providers or patients), recordkeeping (e.g., if RFID is used for maintenance of records required to comply with FDA regulations), privacy (e.g., if RFID tags remain active after dispensing), and product quality (e.g., stability of susceptible drugs exposed to electromagnetic radiation associated with RFID) issues in the pharmaceutical industry that may need to be addressed differently, or not at all, in other industries (e.g., consumer products, electronics).

With regard to privacy and advertising, two areas of interest to the FTC, standard setting is a place where the specific needs of certain industries could be appropriately addressed. For example, standards concerning data contained on the RFID tag, data storage and access, tag encryption, and deactivation or blocking of tags may be different for the pharmaceutical industry than for other industries.

We also recommend that the FTC continue to consult with stakeholders, including appropriate federal agencies, as it reviews this issue.

We thank the FTC for giving us this opportunity to submit comments on this exciting and promising technology.

Sincerely,

William K. Hubbard
Associate Commissioner for Policy and Planning