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Radiofrequency Identification Feasibility Studies and Pilot Programs for Drugs

Guidance for FDA Staff and Industry

Compliance Policy Guides

Sec. 400.210

**Radiofrequency Identification Feasibility Studies
and
Pilot Programs for Drugs
November 2004**

**U.S. Department of Health and Human Services
Food and Drug Administration
Office of Policy
Office of Regulatory Affairs
Office of Enforcement
Division of Compliance Policy**

Preface

Public Comment:

At any time, interested persons may submit written comments regarding this document to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. The comments are to be identified with the title of this guidance document. Such comments will be considered when determining whether to amend the current guidance. For questions regarding the use or interpretation of this guidance, contact the Office of Policy, Paul Rudolf, M.D., J.D. 301-827-3360.

Additional Copies:

Submit written request for a single copy of this guidance to the Division of Compliance Policy (HFC-230), Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857 -001, or FAX your request to 240-632-6861. A copy of the guidance may also be downloaded to a personal computer with access to the Internet. The Office of Regulatory Affairs' home page includes the guidance and may be accessed at http://www.fda.gov/ora/compliance_ref/cpg/default.htm.

**Sec. 400.210
Radiofrequency Identification Feasibility Studies and Pilot Programs for
Drugs**

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You may use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

Background:

Recently, FDA has received inquiries focusing on whether certain regulatory requirements, including those related to labeling,¹ electronic records, and product quality, apply to pharmaceutical manufacturers, repackagers, relabelers, distributors, retailers, or others who participate in feasibility studies and pilot programs (collectively "a study" or "studies") using Radiofrequency Identification (RFID) tags for drugs. This Compliance Policy Guide (CPG) describes how we intend to exercise our enforcement discretion regarding certain regulatory requirements that might otherwise be applicable to such studies. The goal of this CPG is to facilitate the performance of RFID studies and allow industry to gain experience with the use of RFID. As we explained in our report "Combating Counterfeit Drugs" published on February 18, 2004 (which is available on our website at <http://www.fda.gov/oc/initiatives/counterfeit/>) we believe that use of RFID technology is critical to ensuring the long-term safety and integrity of the U.S. drug supply.

Policy:

To the extent that it may be necessary, FDA intends to exercise enforcement discretion as described below for studies that fall within all of the following parameters:

- A manufacturer, repackager, relabeler, distributor, retailer, or others acting at their direction will attach RFID tags (chips and antennae) to only immediate containers, secondary packaging, shipping containers, and/or pallets of drugs that are being placed into commerce. There is no limit to the number of tags or readers that may be used in the study.
- The drugs involved will be limited to prescription or over-the-counter finished products. The drugs involved will not include those approved under a Biologics License Application or protein drugs covered by a New Drug Application.² The study need not have a pre-determined time limit or endpoint, except that tag placement for the study will be completed by December 31, 2007.
- RFID will be used only for inventory control, tracking and tracing of products, verification of shipment and receipt of such products, or finished product authentication.
- RFID will not be used to fulfill existing FDA regulatory requirements (e.g., fulfillment of labeling or Current Good Manufacturing Practice requirements, provision of chemistry, manufacture, and control information, storage of information in fulfillment of a regulatory requirement, or performance of label and product reconciliation).
- RFID will not be used in lieu of current labeling control systems to ensure correct labeling processes.
- The study will use "passive," "semi-active," or "active" tags.³
- Information will be written to the tag at the time that the tag is manufactured (e.g., "read only" tags), after the tag is manufactured but before it is affixed to a drug's container (e.g., "read-write tags"), or after the tag is affixed to a drug's container.⁴ The tags will contain a serial number (e.g., an electronic product code) that uniquely identifies the object to which the tag is attached, and may also contain other information such as storage and handling conditions, information from the FDA approved label and labeling, lot number, and product expiration date.
- The tags will not contain or transmit information for the healthcare practitioner.
- The tags will not contain or transmit information for the consumer.
- The tags will not contain or transmit advertisements or information about product indications or off-label product uses.
- A seal containing a logo, an inventory control message unrelated to the product (e.g., a message informing the custodian that the package contains an RFID tag), and/or a unique serial number may be placed over the RFID tag or elsewhere on a drug's immediate container, secondary packaging, and/or shipping container.

- The addition of the RFID tag and seal will not block, obscure, or alter any of the product's existing and approved label and labeling information.
- The RFID tag will not substitute for, replace, or interfere with a linear bar code required pursuant to 21 C.F.R. § 201.25.
- Participants will "read" the tags as needed to identify the product and/or conduct the study.
- The tag readers will work by emitting electromagnetic energy at radio frequencies of 13.56 megahertz, 902-928 megahertz, or 2.4 gigahertz, and at powers in compliance with regulatory requirements of the Federal Communications Commission (i.e., 1-4 watts effective isotropically radiated power).

If a study is in compliance with all of the parameters listed above, FDA intends to exercise enforcement discretion by not initiating a regulatory action on the basis that the study fails to comply with any of the following regulatory or statutory requirements (to the extent they apply) of the Federal Food, Drug, and Cosmetic Act (the Act) when those requirements are triggered by the use of RFID in the study. The agency intends to limit its exercise of enforcement discretion to those regulatory issues that are specifically triggered by RFID (that is, triggered by the use of RFID readers, the addition of RFID tags, or the placement of seals):

- Any RFID-triggered requirements of 21 C.F.R. & 314.70 and section 506A of the Act.
- Any RFID-triggered submission requirements under 21 C.F.R. part 314 and section 505 of the Act, except for field alert report requirements.
- Any RFID-triggered requirements of 21 C.F.R. part 11.⁵
- Any RFID-triggered requirements of 21 C.F.R. parts 210 and 211 and section 501(a)(2) (B) of the Act (current Good Manufacturing Practices).⁶
- Any RFID-triggered requirements of 21 C.F.R. part 207 and section 510 of the Act (Registration and Listing).

FDA expects that all of the drugs included in these studies will comply with all applicable provisions of the Act in all other respects, and we are prepared to initiate regulatory action if they do not.

This policy expires automatically on December 31, 2007, although we may change our policy sooner or deviate from it in particular cases in order to protect the public health. The December 2007 date should provide sufficient time for industry to gain experience with RFID technology. Furthermore, in our report "[Combating Counterfeit Drugs](#)" we stated that we expect RFID technology to be in widespread commercial use in 2007. When RFID is used outside of the parameters described above, we expect full compliance with all applicable FDA requirements. If RFID technology is used outside of those parameters and does not comply with applicable requirements, we do not expect to exercise enforcement discretion.⁷

Issued: November, 2004
Expires: 12/31/2007

Footnotes

¹ Sections 201(k) and 201(m) of the Federal Food, Drug, and Cosmetic Act define "label" and "labeling" respectively. RFID tags may fall within these statutory definitions in certain instances, but we decline to make a definitive pronouncement on that issue for purposes of this guidance.

²At this time the agency does not have the necessary scientific data to extend its exercise of enforcement discretion to RFID studies for all products. We are in the planning phase of

scientific collaborative studies with industry and academic institutes to evaluate the potential impact of the exposure to RFID associated electromagnetic energy on the quality of a variety of pharmaceutical products.

³A passive tag draws all of its power from the radio waves transmitted by an RFID reader. A semi-active tag uses a battery to run the microchip's circuitry, but not to communicate with the RFID reader. An active tag is powered entirely by battery to send and receive RFID information.

⁴Writing to a tag before it is affixed to a container increases the risk of product mix-ups. We suggest that industry and other interested parties explore the feasibility of writing to the tag after it is affixed to the container.

⁵We believe it is unlikely that studies described in this guidance will trigger any Part 11 requirements. Nevertheless, we intend to exercise enforcement discretion to the extent that Part 11 is triggered. This enforcement discretion policy includes those Part 11 requirements for maintaining the security of electronic records. However, we recommend that parties using "read-write" tags take precautions to ensure the unique serial number and any other information contained in the tag cannot be deleted from the tag or modified in any way (e.g., that the tags be locked).

⁶All other adulteration requirements relating to product quality continue to apply, including sections 501(b) and (c) of the Act. Therefore, sponsors and participants in RFID studies should make a determination as to what, if any, product quality testing should be performed to assess the effects, if any, of the electromagnetic energy associated with RFID on the drug products used in the study.

⁷In order to decide whether to exercise enforcement discretion for studies that do not fall within the parameters of this guidance, we would need to review such studies on a case-by-case basis. The Agency is currently reviewing the regulatory requirements that apply to the use of RFID outside of the study context.

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