

February 24, 2006

Division of Dockets Management (HFA-305)
Food & Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852
<http://www.fda.gov/counterfeit/>

Docket Number: 2005N-0510

Dear Sirs:

The following are comments from Amgen Inc. in response to the Anti-Counterfeiting Drug Initiative Workshop and Vendor Display, held February 8-9, 2006 in Bethesda, Maryland.

Amgen's mission is to discover, develop and manufacture medicines that dramatically improve people's lives. Amgen's FDA approved products have been proven safe and effective pursuant to the FDA standards for use within labeling instructions and have helped millions of patients facing grievous illnesses.

Amgen takes the issue of counterfeit drugs very seriously and is committed to the highest standards of drug quality and patient safety. Our brand protection program supports an effective, secure and resilient global supply chain and the overall integrity of Amgen's medicines for the protection and safety of our patients.

We would like to focus on one simple message in these comments: **FDA should refrain from creating any requirements related to the adoption of RFID technology for biotech products at this time, because to do so could act as a barrier to the supply of important medicines to patients.**

The following three supporting points are discussed below:

1. Because biotech products are liquids and their packaging contains metal, RFID systems may not be accurate or effective for use in a commercial distribution environment at this time for this type of product.

2. Because RF radiation may produce thermal and non-thermal effects in biological products, potentially compromising our medicines, it is premature to require RFID in commercial distribution of these products.

3. Significant standards, infrastructure and business practice issues remain unresolved, making the imposition of RFID requirements premature.

- I. Because biotech products are liquids and their packaging contains metal, RFID systems may not be accurate or effective for use in a commercial distribution environment at this time for this type of product.

The following narrated photographs illustrate the difficulty that is encountered in attempting to read commercially available RFID tags when used with one of Amgen's typical products (Epogen).

The bench top set up consists of an RFID antenna on the left, which emits RF energy, activating the tags attached to the different demonstration products, and picks up (or fails to pick up) any response emitted by the tags. The output is displayed on the computer screen on the right. *(In order to protect the RFID manufacturer's Intellectual Property rights, the computer screen output has been substituted with graphics. However, the graphic responses accurately reflect the system's performance.)*

- The effect of liquids

Figure 1 shows the system reading an UHF RFID tag on a test bottle.

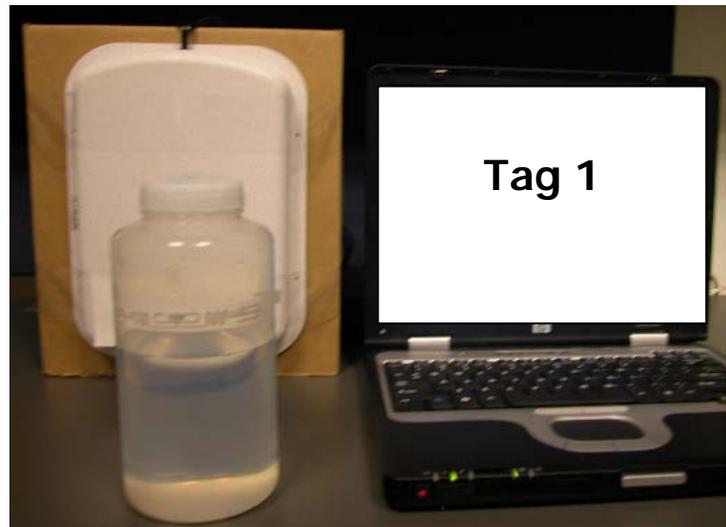
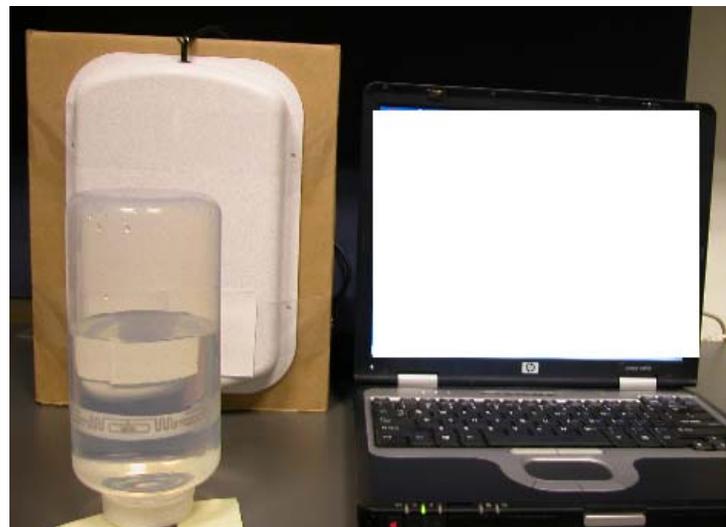


Figure 2 shows the same system unable to pick up the presence of the UHF tag when the liquid comes in closer (but not physical) contact with the tag.



- The (in)ability to read packs of product

Figure 3 upper, shows the contents of a unit of sale box of Epogen with an RFID tag. The lower shows packs of Epogen containing 10 units of sale each with an UHF tag attached.



Figure 4 shows that the RFID system picks up signals from only 3 of the 10 units of sale in the pack.



- The difference with dry product

Figure 5 shows a similar setup with dry product where no metal is present. In this case the system picks up all ten tags.



The preceding is an illustration of the practical difficulty presented by the physics of RF radiation and its interaction with liquids and metals. In preliminary engineering tests, performed by a laboratory testing company at Amgen’s request, using commercially packaged product and industrial testing equipment we found that RFID systems used with our product are not necessarily accurate. The testing results showed that “Consistent 100% readability has not been achieved on conveyor testing.”

The conclusion that we draw from this work is that RFID systems as applied to liquid biological products are still in development and as such should not be required for use with these products.

- II. Because RF radiation may produce thermal and non-thermal effects in biological products, potentially compromising our medicines, it is premature to require RFID in commercial distribution of these products.

The FDA and others have noted that RF energy absorption can potentially cause thermal and non-thermal effects in biological products.¹ If these effects are significant, they could potentially affect the stability of the medicines involved, thereby potentially compromising their safety or efficacy.

Amgen and other organizations have begun to investigate this question but, to date, there does not appear to be an agreed protocol for testing. Without resolution of this issue, it is premature for the FDA to require the use of RFID with biological products.

The FDA’s Radiofrequency Identification Feasibility Studies and Pilot Programs for Drugs document excludes drugs approved “under a Biologics License Application or protein drugs

¹ See: http://www.fda.gov/oc/initiatives/counterfeit/rfid_cpg.html (footnote 2)

covered by a New Drug Application” because “[a]t this time the agency does not have the necessary scientific data to extend its exercise in enforcement discretion to RFID studies [for these products].²

III. Significant standards, infrastructure and business practice issues remain unresolved, making the imposition of RFID requirements premature.

In addition to the special issues noted above related to biologics, there are a number of basic standards, infrastructure and business process issues that should be resolved before the FDA considers any RFID related requirements. These issues were addressed by several presenters at the Feb. 8/9 Workshop.

Just as the approval and manufacture of medicines is an exacting undertaking, the distribution of lifesaving drugs requires careful planning, execution and validation. Given the current unproven nature of reading RFID tags on liquid products, the question of possible product interactions and the various unresolved business issues, Amgen urges FDA not to impose requirements in this area prematurely. To do so could complicate or even cause disruption of the distribution of life saving products needed by patients.

Sincerely yours,
Lewis T. Kontnik
Director, Brand Protection/Business Continuity
Amgen Inc.

² Id.