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Division of Dockets Management
HFA-305
Food & Drug Administration
5630 Fisher Lane
Room 1061
Rockville, Maryland 20852

RE: Honeywell Specialty Films Healthcare Packaging comments on FDA Counterfeiting Drug Task Force Interim Report; October 2003

We are pleased to submit these comments on behalf of the Specialty Films Healthcare Packaging division of Honeywell International (Honeywell). Honeywell is a diversified technology and manufacturing leader, serving customers worldwide with aerospace products and services, control technologies for buildings, homes, and industry, automotive products, power generation systems, specialty chemicals, fibers, plastics, and electronic advanced materials.

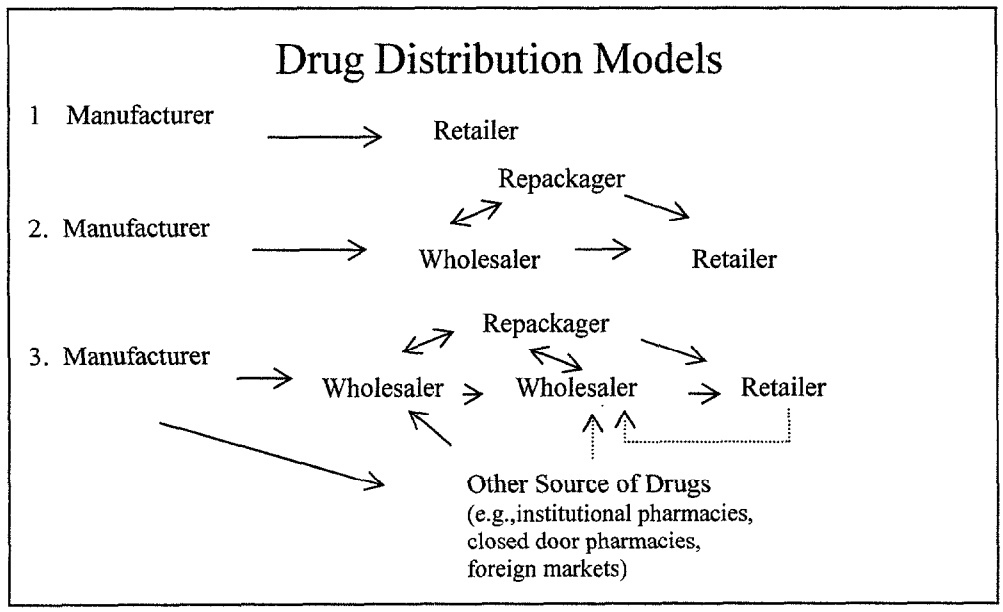
Honeywell applauds the FDA for both recognizing the danger of counterfeit drugs and establishing a task force to address this serious issue. We also appreciated the opportunity to participate, as part of the Healthcare Compliance Packaging Council, in the FDA's October 15th public meeting on the Interim Report.

The experience of Honeywell's Specialty Films Healthcare Packaging division is in providing unique pharmaceutical packaging materials and packaging solutions. Many major pharmaceutical companies use Honeywell's moisture barrier films for unit-dose packaging. In the comments below, we would like to submit our views on the following issues:

(1) The FDA's analysis should be based on the complete distribution model.
(2) Use of unit-dose packaging, enhanced with patient-compliant features, will help to combat anti-counterfeiting.
(3) Drug counterfeiting can be combated with "intelligent-packaging" (eg.RFID, bar-coding, etc.).
(4) Generic drug manufacturers should be included in FDA's analysis of counterfeiting issues.
(5) Anti-counterfeiting technology can enhance professional and patient education.
(6) The costs of anti-counterfeiting measures should be evaluated in the context of the benefits.
(7) The FDA should address several data gaps.

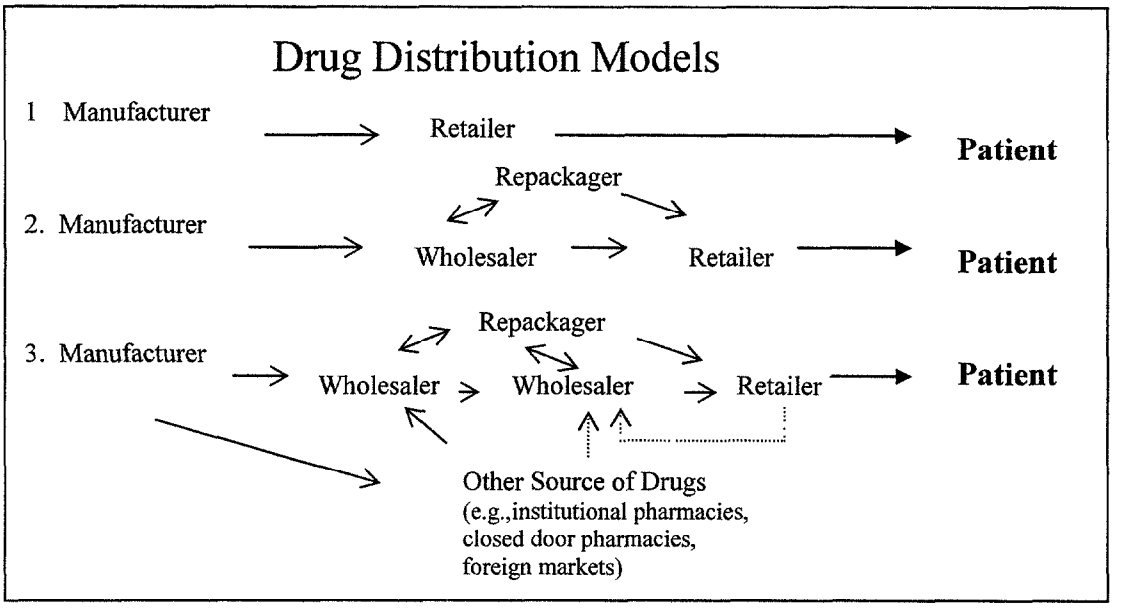
(1) The FDA's analysis should be based on the complete distribution model.

On page 8, figure 1, of the Interim Report, the following drug distribution model is shown:



This diagram represents the various pathways of drug distribution from manufacturer to retailer. As described on page 10-13 of the Interim Report, this diagram helps to identify the "many points of vulnerability" in the model, such as incomplete pedigree, inadequate authentication, importation, re-packing, and tamper evidence issues.

Honeywell believes that a significant stage of the distribution model is missing from this diagram, specifically, the last stage of distribution from the retailer to the patient. As shown in the revised diagram below, the patient is at the end of each possible distribution pathway. While counterfeiting issues may predominate in the manufacturing and distribution chain, the ultimate impact is on the consumer, or patient. By explicitly noting the patient's role in the distribution model, the FDA can consider the costs and benefits that may accrue to the patient from various anti-counterfeiting strategies. Furthermore, by explicitly noting this in its models, the FDA can consider the "points of vulnerability" -- re-packing, re-labelling, contamination, missed education opportunities – that likewise exist in this final stage of the drug distribution model.



(2) Use of unit-dose packaging, enhanced with patient-compliant features, will help to combat anti-counterfeiting.

Honeywell fully supports the suggestion, made throughout the Interim Report, that the use of unit-of-use packaging is one of the critical components to an overall system to combat counterfeiting. In order to properly explain our position, it is important to clarify the difference between unit-dose packaging (e.g., blisters) and unit-of-use packaging. Unit dose packaging refers to the individual packaging of a dose of medication, such as a pill enclosed in a blister package. Unit-of-use packaging refers to the packaging of a prescribed regimen of medication. For example, unit-of-use packaging can be either a blister pack or a bottle containing the prescribed regimen of medication.

The unit-of-use blister package provides advantages to the pharmaceutical manufacturing industry as well as the healthcare provider and the patient not afforded by bottles. These advantages include, but are not limited to, the following:

- **Better Portability** - To aid in maintaining proper dosing when away from home;
- **Tamper evidence** - For obvious pilfering or review of product consumption;
- **Improved efficacy control** - Individually wrapped dose for better stability;
- **Improved drug storage stability** - Each dose stays packaged until consumed;
- **Child resistant properties** - Once opened only one dose is exposed to a child;
- **Calendar Pack** - Enhanced compliance features for improved medication persistence;
- **Larger labelling area** – Allows for additional & larger content of easy-to-read educational messages to advise and protect patients. Can draw attention to anti-counterfeiting properties that older patients can see;

- **Overt and covert RFID features** – Traceability (such features can be imbedded in the package without contacting the drug itself); and
- **Halographics on lidstock foils and non-foil surfaces** – Allows for additional overt anti-counterfeiting opportunities when using blister packaging.

Honeywell has been working directly with pharmaceutical companies for many years regarding packaging solutions for ethical pharmaceutical products and OTC products. We have learned that the industry is well aware of medication compliance issues. It is our belief that the use of compliance enhanced, blister calendar, packaging can enable the healthcare provider and the patient to work more closely together. By utilizing a compliance concordance model the provider and patient can help alleviate the effects of the increasing costs of pharmaceuticals in our economy today. Blister packaging can also aid the pharmacist by providing a tool for reducing medication-dispensing errors (miscounting, etc). Additionally, unit-dose package design can provide an educational tool for the pharmacist when interacting with the patient. Finally, the manufacturer can provide a package that requires no additional repackaging and can be trademarked and traced to achieve market differentiation. A trademark provides a 'direct to customer' communication tool that supports the overall anti-counterfeiting campaign.

Honeywell recently held focus group events to better understand the preferences and perceptions of patients and industry experts regarding packaging options (including blister and compliance enhancing features). The groups consisted of pharmacists, nurses, elderly patients (60-75 years of age) and parents (30-55 years of age). Although our information remains proprietary, we would like to share the following general conclusions:

O The group most interested in compliance enhanced blister packaging is the 30-55 year old individual, who can be a patient, a caregiver, and/or a parent. This group, comprised of busy people who want a convenient but safe way to take their medication correctly, sees significant benefit in having unit dose packaging with compliance features.

The nurses and pharmacists agreed that compliance enhancing, unit-dose packaging could provide a means to spend more time with the patient. A pharmacist can spend less time counting and packaging a patient's unit of use and more time talking to the patient about following the treatment regimen. An added benefit is that unit-dose packaging eliminates potential counting errors by the pharmacist.

O The other key learning from the focus groups was that unit-dose packaging enhanced a patient's understanding of compliance with a prescribed treatment regimen. When participants (other than pharmacists) were asked if they knew the definition of compliance, no one did. However, when a currently marketed antibiotic brand product, in a compliance-enhanced, unit dose pack was mentioned, everyone understood the meaning of compliance and recognized the importance of the package. It appears to us, therefore, that pharmaceutical

companies have a real 'value-added' opportunity with unit dose, compliance-enhancing packaging.

(3) Drug counterfeiting can be combated with "intelligent packaging" (i.e RFID, bar-coding, etc.).

The combination of unit dose packaging (with compliant features) and radio frequency identification (RFID) is certainly an option that Honeywell supports as part of the solution to combat counterfeiting. We want to make sure that the benefits of RFID technologies get implemented not just for the supply chains but also for the benefit of the end user or patient. We believe that there can be technology available in the near-term that will also provide some benefits to offset the anticipated increased costs of these technologies.

RFID is currently being touted as the next-generation bar code, allowing companies to significantly streamline their supply chain. In the near-term (12-24 months), passive RFID will be integrated down to the pallet level. Most companies suggest that the current and near-term costs of passive RFID will be too great for implementation at the item level. It is our view that the integration of passive or semi-active RFID integrated at the item level (e.g., on a blister card) will offer significant advantages above and beyond the supply chain benefits of RFID on pallets. The incorporation of a semi-active RFID tag into a blister card with sensors for temperature and humidity would allow the package shelf life to be determined, and hence the efficacy of the drug to be monitored and maintained. It would also allow for individual tracking of the package to assure the caregiver, whether a doctor, pharmacist, nurse or even a parent, that the correct drug and dosage are being administered. Even though current RFID technologies are expensive, the technology is currently available to provide packaging readers at a pharmacy or even in one's home medicine cabinet.

In addition, the RFID tag can be used to store drug information for educational purposes. The integration of an RFID tag into the unit-dose package film would permit counterfeiting deterrence and provide tamper evidence. Thus, in our perspective, the higher costs associated with RFID could be significantly offset by the compliance enhancing and security benefits of these technologies.

(4) Generic drug manufacturers should be included in FDA's analysis of counterfeiting issues.

The generic pharmaceutical manufacturing business segment is growing and evolving rapidly. Generics companies are becoming critical suppliers of prescription drugs, as evidenced by double-digit growth since 2001. We are aware of the perception that counterfeiting has been a problem primarily with branded drugs. We also recognise that generic drug manufacturers may be more resistant to the additional costs associated with anti-counterfeiting technologies. However, as generic drugs continue to grow in popularity, and as drug counterfeiting activities become more prevalent and sophisticated, consumers of generic drugs face an increased threat of the risks of counterfeit drugs. Furthermore, as the costs of anti-counterfeiting technologies decline, generics companies will be able to fully participate in the fight against counterfeit drugs. From the patient's perspective, protection from drug

counterfeiting should not depend on whether the patient is taking branded or generic drugs. Educating the patient to recognize and protect themselves against counterfeit drugs becomes more difficult if the source and look of their medication is changing from prescription to prescription. At a minimum, the FDA should include generic drugs in its analysis of the counterfeit drug problem and potential solutions.

(5) Anti-counterfeiting technology can enhance professional & patient education.

Honeywell also agrees that packaging can and should provide a format for better education of the healthcare provider and the patient. Unit dose, compliance-enhancing packaging can become the in-home 'billboard' for educating the patient, the caregiver, and even the pharmacist or doctor dealing with a new drug or treatment. It can be a great tool for the pharmaceutical sales person to promote all the benefits of physician sample, compliance, blister packaging (with anti-counterfeiting properties) to the healthcare provider. Ultimately, the healthcare provider has a tool to demonstrate the same features and benefits to the patient. By utilising the same packaging features to the trade pack, the pharmacist can properly and timely provide consultation to the patient at the time of refill. In the near future, this can be more completely enabled using RFID tags scanned at home via computer, a small handheld device, or even a cell phone to read additional educational materials.

(6) The costs of anti-counterfeiting measures should be evaluated in the context of the benefits.

Understanding the cost model is critical for dealing effectively with the drug counterfeit problem. As noted on page 18 in the Interim Report, the proposed options bring siginificant potential cost increases, as well as numerous significant benefits. Honeywell believes that by combining an anti-counterfeiting technology, such as RFID technology, with unit-dose packaging, which has inherent compliance enhancing features, the benefits will grow significantly and help offset cost increases. Drug related issues have been, in part, responsible for the more than 100% increase in healthcare economic expenditures between 1995 and 2002. Adverse drug effects, poor medication compliance, even patients failing to get their prescriptions filled, have all contributed to the increased costs of healthcare. Could packaging design improvements aid in dealing with these issues? Could compliance enhancing packaging that contains anti-counterfeiting properties along with child resistant properties and educational messages that promote persistence be a better choice then today's model? Honeywell believes the right combination of packaging can help to provide benefits commensurate with the increased costs of anti-counterfeiting initiatives.

(7) The FDA should address several data gaps.

Certain data is needed to help address the many questions noted in the Interim Report as well as to help drive this initiative. We note two specific data gaps:

A) Today's industry cost model vs. tomorrow's industry cost model with the proposed packaging changes. This information should help answer questions

such as: How much better will the healthcare provider be able to educate and prescribe proper medicines because of its enhanced package design? How do we measure any decrease in drug related issues if patients become more complaint with their medication with the adoption of improved packaging? How will the liability insurance costs be effected at the pharmacy retailer if they only manually count 30% of their prescriptions drug vs 80 %? Will liability insurance decrease? What additional revenue will the pharmaceutical manufacturer make from added sales due to enhanced compliance and reduced levels of counterfeiting? These are just a few questions; there may be many more benefits once the costs are properly accounted for through the entire value chain.

B) Anti-counterfeiting efforts need to be prioritized; the best candidates for such initiatives need to be identified. We do not advocate that everything needs to go from a bottle to a unit dose blister. We recognize that the costs of anti-counterfeiting initiatives are likely to be expensive and that initiatives for all drugs cannot be implemented at once. Therefore, some effort must be made to prioritize the needs for anti-counterfeiting measures. This effort will require gathering data on the uses of various drug segments and entitities, and the potential risk of counterfeiting.

Conclusion

In conclusion, the four fundamental goals and purposes of the FDA anti-counterfeiting task force will require many resources, in many areas. Honeywell, along with many others, are willing to provide the support needed to help address this serious issue, which affects us all professionally and personally. We agree that there is no "magic bullet" today but with a combination of options, noted in the Interim Report and reiterated in our comments on value-added benefits to the patient, Honeywell believes that the healthcare industry can successfully combat counterfeiting efficiently and economically.

Sincerely,

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