Selig – the leading global manufacturer of cap and closure lining materials for use across a broad range of applications including pill bottles – is working on a pioneering package seal for medication that will offer enormous benefits, especially to the elderly/impaired, but also to the general population.

The package seal – called Top Tab™ 2 TamperSeal – is a liner for containers in the US market that hold pharmaceuticals, nutraceuticals and over-the-counter (OTC) medicines. Packaging for this sector requires seals with these important features:

- A tamper evident seal (to indicate whether the packaging has been interfered with)
- A hermetic seal (to protect the container’s contents)

Consumer convenience (easy opening for those with physical limitations) and improved hygiene (less chance of introducing pathogens to the package) to date has not been a requirement as achieving all these features in a single product has been quite challenging. For example, there might be a conflict between easy opening and a tamper evident seal (which requires a powerful ‘weld’ of the foil to the bottle). There are also situations where breaching the tamper evident liner requires the use of a tool, which may risk the introduction of microbes to the package. Top Tab™ 2 TamperSeal is designed to offer all these features with none of the incompatibilities.

Tamper evident (TE) packaging
In North America, most OTC drugs (including analgesics, decongestants, antihistamines, and similar products) are frequently sold in plastic containers. The same types of containers are often used for vitamins, minerals and nutraceuticals. In the US, these products need to be in tamper-evident packaging, that are designed to reveal any interference with the contents.

This requirement goes back to what were dubbed the ‘Chicago Tylenol™ murders’, a series of fatalities resulting from malicious drug tampering in the Chicago area in 1982. Seven people died in the original poisonings, with several more deaths in subsequent copycat crimes. The victims had all taken Tylenol™ paracetamol capsules deliberately laced with potassium cyanide.
In response to this horrific incident, the US Food and Drug Administration (FDA) introduced regulations requiring tamper resistant packaging for such OTC products, together with appropriate labelling to allow the end consumer to confirm before use that the packaging has not been compromised. The regulation (21 CFR Vol 4 Section 211) notes that a tamper resistant package as “…one that has one or more indicators of barrier to entry, which, if breached or missing can reasonably be expected to provide visible evidence to consumers indication that tampering has occurred.”

Tamper-evident features on primary and secondary packaging include shrink wrap films, bands or wrappers, boxes with tamper-evident security seals and breakable caps. One of the first tamper-evident technologies noted in the guidelines for rigid containers was induction cap sealing (‘inner seals’).

Furthermore, in the DRUGS AND THE PHARMACUETICAL SCIENCE series of Textbooks and Monographs, Volume 169, 6th Edition, the author notes “Container Mouth Inner Seals…applied by heat induction to plastic containers appear to offer a higher degree of tamper-resistance than those that depend on an adhesive to create the bond.”

In this same Volume (Packaging Systems Section A.6.) ‘inner seals’ which provide tamper resistance are further described as: “Paper, thermal plastic, plastic film, foil, or a combination thereof, sealed to the mouth of a container (e.g., bottle) under the cap. The seal must be torn or broken to open the container and remove the product. The seal cannot be removed and reapplied without leaving visible evidence of entry.”

Induction sealing uses a multi-layer laminated liner inside the container cap. Once the cap is seated, aluminum foil within the liner is heated by electromagnetic induction, causing a layer of heat seal material to bond securely to the rim (or land area) of the container. This creates a strong, hermetic, tamper-evident seal.

Induction liners are highly-engineered layered laminate structures. Typically, they include a heat seal layer, chosen to match the material of the underlying container, a layer of aluminum foil to generate heat through induction and act as an oxygen and moisture barrier, and a backing material for rigidity and to provide a reseal feature.

In both OTC and other applications, the upper layers can be printed for branding or health advisories, or employ overt or covert anti-counterfeit features, such as etched or holographic films. Some of these applications can also use a liner with a structure to allow easier access to the contents, but still requires puncturing through a layer of material with a finger or tool. The Top Tab™ 2 TamperSeal product is constructed with the typical Lift ‘n’ Peel™ half-moon center tab for ease of removal.

**Hermetic seals**

As well as tamper evidence, most OTC medicine containers also need a hermetic seal, an effective gas and moisture barrier, to prevent the contents degrading in the case of oxygen ingress, or gumming up if moisture enters the container.

Hermetic sealing also helps maintain the freshness of some products for longer, prevents leakage and protects against pilferage.

**Consumer convenience & improved hygiene**

A potential problem with hermetic sealing on medicine containers is that the strength of the seal might mean younger or older consumers don’t have the hand strength, dexterity or the necessary hand eye coordination to break the seal. This may require the use a tool or knife, which introduces the risks of injury as well as the introduction of microbes from the tool to the package contents and/or the residual lining material left on the container.

Besides, how easy or difficult packaging is to open can affect purchasing decisions and could cost businesses dearly in terms of lost customer goodwill and therefore revenue.
Top Tab™ 2 TamperSeal
Tamper evidence, Hermeticity, Convenience & Improved Hygiene
Selig is targeting the development of Top Tab™ 2 TamperSeal to ensure that tamper evidence, hermetic sealing, ease of opening as well as improved hygiene are met. Top Tab™ 2 TamperSeal has the same half-moon tab as Selig’s Lift ‘n’ Peel™ and it is bonded directly to the container to achieve a gas and moisture-tight seal. However, it also “destroys itself”, as it were, when removed from a container and therefore shows tamper evidence on the land area of the container (on which foil remains).

Barriers to entry and call to action
Approximately 20% of the induction sealing market in North America comprises the OTC/pharmaceuticals market. However, although the Top Tab™ 2 TamperSeal product is an attractive proposition for containers holding OTC medicines, it is not simply a case of developing it and offering it to the marketplace.

First, it is a significant technical challenge. If you ‘induction-weld’ a seal to the container and try to pull it off, the weakest link will break. To prevent the half-moon tab from ripping off or the liner delaminating and leaving internal layers still covering the bottle orifice, the lamination strength at the bottle land area has to be the weakest link. That is why Selig have made the tab stronger than the bond in that area.

Secondly, the contents of the bottle need to be known as the liner can be different depending on the chemical formulation of the product in the container. For example, if it is a cough suppressant, is the liquid acidic? That will affect the materials used for the foil seal. OTC analgesics are regulated drugs so they and their packaging materials must go through FDA testing. There is inevitably product contact and if anything hazardous can migrate out of the adhesive or foil into the product, then that’s a problem.

Finally, the design of each liner/foil seal depends on the container material. For example, the container might be made from polyethylene terephthalate (PET) often used on clear bottles for liquids; containers for dry products (powders, pills, etc.) often employ high-density polyethylene, or polypropylene. The surface of the liner that bonds to the container is formulated specifically for that container resin.

So when specifying Top Tab™ 2 TamperSeal, Selig needs to know the contents of the container, the filling conditions, and the material from which the container is made. For these reasons, Selig is looking for partners with specific applications in mind to commercialize the Top Tab™ 2 TamperSeal product. If your company wants to overcome these pharmaceutical packaging challenges, please contact Selig (email jbrown@seligsealing.com).

Improved safety & hygiene - punctured seal vs peeled seal

Traditional Seal
TamperSeal
About Selig
Selig is a leading worldwide manufacturer of tamper evident cap and closure lining materials for use across a broad range of applications; such as food and beverage, pharmaceutical, agrochemical, cosmetics and healthcare. Selig’s comprehensive range of both one and two piece structures means that they can manage even the most challenging applications with one of their customized aluminum foil/heat seal combination products. In addition, Selig offers a range of easy open products, which offer greatest convenience and product freshness to consumers as well as strong market differentiation to the brand owner.

Further information
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