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Source: Colorcon Inc.

FDA Draft Guidance Document Comments on Use of Inks, Pigments, Flavors and Taggants to Guard Against Counterfeiting

WEST POINT, Pa., Aug. 10, 2009 (GLOBE NEWSWIRE) -- Colorcon, Inc. announced this week that the Food and Drug Administration's "Guidance for Industry Incorporation of Physical-Chemical Identifiers into Solid Oral Dosage Form Drug Products for Anticounterfeiting" issued on July 14, 2009, provides recommendations for pharmaceutical manufacturers on the use of inks, pigments, flavors, and various taggants used as physical-chemical identifiers (PCIDs) in non-functional (immediate release) film coatings. The FDA guidance covers regulatory filing requirements for the usage of PCIDs on products currently being film coated, and also includes information on the type of supporting documentation required for new drug applications (NDAs), abbreviated new drug applications (ANDAs) and other post approval changes for incorporation of PCIDs.

Exclusive Tablet Identification and Authentication Systems from Colorcon

Pigments, Flavors and Inks

Colorcon offers a complete line of customized film coating and ink formulations that can be used to give a unique appearance to solid oral dosage forms (SODFs) -- making it easier for a patient or pharmacists to identify the product at a glance. These excipients offer established safety profiles, do not interact with core components, and have no potential effect on the quality, performance, and stability of the SODF -- all of the important pharmacological and toxicological considerations covered in the FDA guidance document. Plus, incorporating a customized film coating such as a pearlescent film coating, coatings containing unique flavors, or the addition of an ink-imprinted logo as part of a tablet design, which do not interact with core active ingredients, are covered in the document as a first-line of defense against counterfeits. Use of these technologies make drugs difficult to fake and can assist patients in identifying counterfeits before they take them.

Tablet Design

In the past, a particular color alone might have afforded significant counterfeit protection, but in today's global market, that is no longer the case. However, unique shape, size and logo combinations often provide trademark protection, which are also useful as a first line of defense against counterfeiters. Colorcon's Brand Enhancement Service(TM) assists companies in the design of unique combinations that incorporate accepted authentication technologies, and offers guidance on global regulatory requirements. The designs prove invaluable to pharmaceutical manufacturers in developing a comprehensive, multi-level approach for protecting their brands.

Taggants

Another approach, covered as a PCID in the new guidance document, that pharmaceutical manufacturers are considering, involves adding a trace amount of an inactive ingredient or combination of inactive ingredients to an existing section of the dosage form through a taggant dispersed in the film coating formulation and applied directly to the tablet surface.

An on-dose covert marker technology was developed through an alliance between ARmark Authentication Technologies, developer of custom authentication systems, and Colorcon. The (R)mark(R) On-Dose ID covert micro-tags are custom-developed from approved excipients listed in the FDA's Inactive Ingredient Guide (IIG). They are manufactured by ARmark under cGMP conditions and are considered to be a PCID under the new FDA guidance document. A unique physical-chemical characteristic of the (R)mark(R) micro-tags make it possible to detect and authenticate legitimate dosage forms and identify counterfeits under magnification, yet they are not visible to the naked eye and are virtually impossible for a counterfeiter to reverse engineer.

Because the markers are applied directly to pharmaceutical tablets during existing tablet coating processes, they offer manufacturers total reliability for placement of the markers on each and every tablet. This also allows any company manufacturing film coated tablets to seamlessly apply the micro-tags as part of the film coating process with no additional steps. The addition of the micro-tags as a PCID to immediate release film coatings should be considered a SUPAC Level 1 type of change and would be documented in a company's next annual report. The draft FDA guidance has a detailed listing of the required data and information needed for incorporation of the micro-tags into the immediate release film coating. These requirements can be satisfied by a combination of applicant data and ARmark information incorporated by reference from a Type IV DMF.

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microscope. Various levels of forensic signatures, that would require in-house detection, can also be incorporated for an added level of security.

According to Dr. Kamlesh Oza, Colorcon's General Manager of Film Coatings, "We really feel that companies need to adopt a multi-layer strategy with a combination of unique on-tablet technologies including visual, electronic, forensic and sensory identification. Adopting a multi-layer strategy that includes authentication on the SODF itself will give the pharmaceutical manufacturer added confidence that its products will remain un-adulterated as they travel through the pharmaceutical supply chain. Our customized film coating systems, our alliance with ARmark Authentication Technologies, LLC, and our Brand Enhancement Service, work seamlessly to help our pharmaceutical clients identify the right strategy for their product, take an aggressive role to assure patient safety, and mitigate the risk of adulterated or counterfeited products entering the marketplace."

About Colorcon

Colorcon is a world leader in the development, supply and technical support of fully formulated products for the pharmaceutical and dietary supplement industry. Its core businesses include film coatings, modified release technologies, functional excipients, and tablet branding services. Colorcon has 18 technical service laboratories globally and more than 1200 employees exclusively dedicated to its customer base. For more information on Colorcon capabilities and its products, call 215-699-7733 or visit www.colorcon.com.

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