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### FDA Issues Draft Guidance Regarding the Incorporation of Physical-Chemical Identifiers into Solid Oral Dosage Form Drug Products for Anticounterfeiting

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On July 13, 2009, the U.S. Food and Drug Administration (FDA) issued a draft guidance for industry titled "Incorporation of Physical-Chemical Identifiers into Solid Oral Dosage Form Drug Products for Anticounterfeiting" (the "Draft Guidance"). The Draft Guidance provides recommendations to pharmaceutical manufacturers who are considering using physical-chemical identifiers (PCIDs) to prevent the counterfeiting of solid oral dosage form (SODF) drug products, such as pills and capsules. PCIDs are inactive ingredients with established safety profiles, such as inks, pigments, food additives, colorants, flavors and molecular taggants, that can be incorporated into SODFs to, among other things, make (1) identification of legitimate dosage forms easier and (2) duplication by counterfeiters more difficult.

When incorporating PCIDs, the FDA recommends pharmaceutical manufacturers take into account certain design, pharmacological and toxicological considerations. For instance, ingredients comprising the PCIDs should be relatively inert; pharmacologically inactive; and either be generally recognized as safe (GRAS), be a "permissible direct food additive" or be listed in the FDA's *Inactive Ingredient Guide*. Additionally, a substance used as a PCID should not adversely affect the identity, strength, quality, purity, potency or bioavailability of the SODF. Other considerations include the location of the PCID within the drug and whether the PCID might interfere with control of the release rate of a modified-release SODF. To minimize adverse effects, the Draft Guidance recommends using the lowest level of PCID that ensures identification of the SODF.

The Draft Guidance also includes recommendations describing:

- What supporting documentation should be included in a New Drug Application (NDA) or an Abbreviated New Drug Application (ANDA) premarketing or postapproval regulatory submission that proposes the incorporation of a PCID into an SODF.
- How to report the postapproval incorporation of a PCID in an annual report or submit changes being effected (CBE-30) or a prior approval supplement; and how to perform risk assessments to determine the appropriate reporting category.
- How to revise the packaging and labeling of an SODF to indicate the incorporation of a PCID.
- How to assess PCID toxicology and the potential for an adverse effect on SODF quality, performance and stability.
- Procedures for reporting and requesting approval to add PCIDs to packaging and containers as a postapproval change.

#### For Further Information

If you have questions concerning this draft guidance or would like more information, please contact [Frederick R. Ball](#), any of the other [health law lawyers](#) in the [Pharmaceutical & Biotechnology industry group](#) or the attorney in the firm with whom you are regularly in contact.