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Incorporation of physical chemical identifiers into solid oral dosage form drug products for anti-counterfeiting

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This document is intended to provide guidance to pharmaceutical manufacturers who want to use physical- chemical identifiers (PCIDs) in solid oral dosage forms (SODFs). A PCID is a substance or combination of substances possessing a unique physical or chemical property that unequivocally identifies and authenticates a drug product or dosage form. This guidance provides recommendations to pharmaceutical manufacturers on design considerations for incorporating PCIDS into SODFs, supporting documentation to be submitted in new drug applications (NDAs) and abbreviated new drug applications (ANDAs) to address the proposed incorporation of PCIDs in SODFs, supporting documentation to be submitted in post-approval submissions to report or request approval to incorporate PCIDs into SODFs, and procedures for reporting or requesting approval to incorporate PCIDs into SODFs as a post-approval change. The incorporation of components or features used in radiofrequency identification for drug products is outside the scope of this guidance. In addition, this guidance does not apply to manufacturing or formulation changes, made in conjunction with the addition of a PCID, that go beyond simply inserting the PCID into a blending or mixing operation (e.g., adding a PCID to a non- functional tablet film coating is covered by this guidance, but adding a non-functional film coating that contains a PCID to a previously uncoated tablet involves manufacturing changes that are not covered by this guidance). The incorporation of a PCID into the packaging or labeling is not covered in this guidance. Other guidance documents, which may be applicable to proposed changes outside the scope of this guidance, are located on FDA's guidance Web site 2 and should be consulted to help to determine whether additional reporting or approval procedures may apply to proposed changes outside the scope of this guidance. FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidance documents describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in an Agency guidance document means that something is suggested or recommended, but not required.

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