Anticounterfeiting of Solid Oral Dosage Forms

Hemant N. Joshi, Ph.D., MBA
Tara Innovations LLC
Parsippany, NJ
hemantjoshi@tarainnovations.com
www.tarainnovations.com
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Topics covered

- General information
- Background
- Design considerations
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General Information

- Guidance for Industry – Incorporation of Physical-chemical identifiers (PCIDs) into solid oral dosage form (SODFs) drug products for anti-counterfeiting, US FDA, CDER, October 2011.
- PCID is a substance or a combination of substances possessing a unique physical or chemical property that unequivocally identifies and authenticates a drug product or a dosage form.

Background

- To **counterfeit** means to illegally imitate something. Counterfeit products are often produced with the intent to take advantage of the superior value of the imitated product.
- The main goal here is to thwart drug product counterfeiting

Background

- One of the commonly used approach is to add a trace amount of an inactive ingredient with unique physico-chemical properties which will allow to detect and authenticate the legitimacy of the dosage form and indentify counterfeits.
- Inks, pigments, flavors, molecular taggants

Background

PCIDs are detected by –

- Physical observation (color/flavor)
- Use instruments – laser scanning, microscopy, holography, photolithography, mass spectrometry etc.

Design considerations

- Pharmacologically inactive
- GRAS substances are preferred
- PCID should not act as an allergen
- Use in concentrations recommended in IIG
- PCID should not affect the quality, performance, and stability of drug product
- It should not be located next to drug molecule or next to a functional excipient.

Supporting documents for a proposed incorporation of PCIDs

In Premarketing or post-approval submissions

- Chemical composition of PCID
- Rationale for selection and description of its incorporation in the dosage form and location
- Physico-chemical attributes and specifications
- Impurities in PCID
- Safety justification based on toxicology data

Supporting documents for a proposed incorporation of PCIDs

- Manufacturing steps and controls
- Assurance of quality and performance of product
- Risk assessments associated with the incorporation of PCID

Supporting documents for a proposed incorporation of PCIDs

PCID to be incorporated in products which are already in the market

- Change in the impurity profile of the product Use ICH guidance Q3B(R2) Impurities in New Drug Products
- Data from long-term and accelerated stability studies to evaluate impurity formations in the presence of PCID
- Effect of PCID on the drug release rates/ dissolution profile

Supporting documents for a proposed incorporation of PCIDs

- Effect of PCID on the drug release rates/dissolution profile
- Applicants that propose to incorporate a PCID into a SODF as a post-approval change should submit a CBE-30 supplement or incorporate in the annual report.

Reporting categories

- Prior approval supplement
- CBE-30 supplement
- Annual report

Labeling

- Applicants should review the statute and all regulations to determine how the incorporation of PCID may impact the labeling of their product. PCID may not have to be included in the list of ingredients in a drug's labeling.
- All labeling changes are subject to the submission and approval requirements under 21 CFR 314.70.