BIOTECHNOLOGY INDUSTRY ORGANIZATION
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October 13, 2009

Dockets Management Branch (HFA-305)
Food and Drug Administration
5600 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2009-D-0212

Dear Sir/Madam:

The Biotechnology Industry Organization (BIO) thanks the Food and Drug Administration (FDA) for the opportunity to submit comments on the FDA Draft Guidance on "*Incorporation of Physical-Chemical Identifiers (PC-ID) into Solid Oral Dosage Form Drug Products for Anticounterfeiting*." BIO is pleased that the FDA continues to provide guidance to industry on available tools to combat criminal counterfeiting as part of a multi-layered anti-counterfeiting strategy. We encourage FDA to continue to prioritize the development and adoption of less intrusive technologies, while also ensuring that PC-ID is used on a voluntary, product appropriate basis in a manner that protects the confidentiality of the technical details of covert PC-ID technologies.

BIO represents more than 1,200 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products, thereby expanding the boundaries of science to benefit humanity by providing better healthcare, enhanced agriculture, and a cleaner and safer environment.

Biopharmaceutical supply experts are in a technological "arms race" to stay a step ahead of counterfeiters and the industry has taken productive steps to secure drug and biologic products with numerous and layered anti-counterfeiting technologies. Anti-counterfeiting technologies continuously evolve and change in response to the constantly changing threat of counterfeiting and the technological sophistication of counterfeiters. We are pleased to see that the guidance seeks to empower manufacturers with important

considerations related to the safe use of PC-ID if they decide to employ that particular tool as a product-appropriate element of their comprehensive anti-counterfeiting strategy. However, we note that while PC-ID may be useful tool for deterring counterfeiting of certain small molecule pharmaceutical products, in recent years other less invasive authentication technologies have emerged that would have less direct impact on the safety or efficacy of the product compared to PC-ID. In light of the limited public and private resources available for anti-counterfeiting activities, we hope that the current focus on PC-ID will not detract or distract from the development and adoption of other promising approaches. In particular, BIO supports FDA's efforts to facilitate the establishment of a uniform national e-pedigree/track-and-trace system.

Second, the draft guidance is limited in scope to only oral, small molecule pharmaceutical products, yet some of the concepts proposed in the guidance could potentially be applied to other product classes in the future. We encourage FDA to continue to characterize the use of PC-ID as a strictly voluntary initiative and manufacturers should only consider PC-ID if it is appropriate for their respective product. PC-ID technologies may not be appropriate for other product classes, such as liquid products, and should not become a mandatory regulatory requirement or be applied to all product classes in the future.

Finally, we stress that both FDA and companies that utilize PC-ID should take steps to maintain the confidentiality of the technical details covert PC-ID technologies. If the technical details of a covert PC-ID technology were accidentally disclosed and revealed to criminal counterfeiters, it would seriously jeopardize the utility of that anti-counterfeiting tool. Companies that use these types of covert anti-counterfeiting technologies are extremely sensitive to the dangers of public disclosure and limit employee access to the characteristics of the PC-ID on a strictly "need-to-know" basis. A similar level of confidentiality should be maintained at the FDA. For example, we are concerned that including PC-ID details within a New Drug Application (NDA), Biologic Licensing Application (BLA), or supplement would make this information available to a large number of people both within the company and among FDA reviewers and staff who would not necessarily "need to know." We recommend that sponsors submit PC-ID information as a separate filing with limited distribution within FDA and a firewall could be established to limit inappropriate access to electronic filings that include PC-ID technical details. Alternatively, this type of proprietary information could be maintained in a Drug Master File (DMF) to preserve confidentiality.

BIO appreciates this opportunity to comment on "*Incorporation of Physical-Chemical Identifiers into Solid Oral Dosage Form Drug Products for Anticounterfeiting*." We have also included specific line-by-line comments in the following chart. We would be pleased to provide further input or clarification of our comments, as needed.

Sincerely,

/S/

Andrew J. Emmett
Director for Science and Regulatory Affairs
Biotechnology Industry Organization (BIO)

SPECIFIC COMMENTS

SECTION	ISSUE	PROPOSED CHANGE
Section IV. A	Control of raw materials and their supply chain have heightened visibility in the past several years, especially for the substances that neither appear on the generally recognized as safe (GRAS) list nor are inactive ingredients used in a CDER-approved solid oral dosage form (SODF).	Please consider addressing the material control that should be applied to the PC-ID if the substance in it neither appears on the GRAS list nor is an inactive ingredient already used in a solid oral dosage form.
Line 126:	The impurities that may be present in the PC-ID that contains all substances appearing on the GRAS list or in CDER-approved SODFs from qualified suppliers should impose minimum concern, given the typically small quantity applied.	Please consider focusing on impurities that may be present in the PC-ID if a substance in it neither appears on the GRAS list nor is an inactive ingredient in a CDER-approved SODF.
Line 177:	"Hope" is difficult to use as the basis for action or planning in the regulated industry.	Please revise the phrase indicating "It is our hope..." to "It is our current thinking..."
Lines 183-188:	The addition of examples would make the section consistent with lines 189-193.	Please consider adding examples to this section.