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April 21, 2015

Division of Docket Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Reference: FDA Draft Guidance for Industry Investigating and Reporting Adverse Reactions Related to Human Cells, Tissues, and Cellular and Tissue-Based Products
Docket: FDA-2015-D-0349

Dear Sir/Madam:

PDA finds these recent HCT/P guidance documents to be some of the clearest and well written in this arena and appreciates FDA efforts in this regard. Specifically with respect to this guidance on adverse reactions, PDA believes that adverse event reporting requirements for "Section 361 HCT/Ps" (codified in FDA's regulations at 21 C.F.R. § 1271.350) are in some respects inadequate for today's environment in which tissue products that are produced using large-scale manufacturing processes are being marketed for a wide range of applications other than mere replacement or structural/mechanical repair of damaged or diseased tissues. Currently the adverse event reporting requirements are limited to circumstances involving a communicable disease. However, these products are fully capable of causing a wider range of adverse events, similar to those that may be expected with any drug, medical device or biological product that is implanted in or applied to patients. Because FDA's overarching mission is the protection of the public health, it is critical that FDA begin to track and collect data on these types of incidents, which may impact patients' health even when not associated with communicable disease transmission. The requirements should be consistent with the current requirements for adverse event reporting required for medical devices, biologics and drugs.

PDA is a non-profit international professional association of more than 10,000 individual member scientists having an interest in the fields of pharmaceutical, biological, and device manufacturing and quality. Our comments were prepared by a committee of experts with experience in pharmaceutical, biological and device manufacturing including members representing our Combination Products Interest Group, Regulatory Affairs and Quality Advisory Board, and Board of Directors.

If there are any questions, please do not hesitate to contact me.

Sincerely,

Richard Johnson,
President, PDA



Food and Drug Administration Draft Guidance

Investigating and Reporting Adverse Reactions Related to Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)
Regulated Solely Under Section 361 of the Public Health Service Act and 21 CFR part 1271

April 21, 2015

General Comments	Rationale
<p>This guidance only applies to transmissions of communicable diseases and does not address other types of adverse experience/reaction such as serious injury, serious inflammation, or death related to HCT/Ps.</p>	<p>PDA believes that adverse event reporting requirements for “Section 361 HCT/Ps” (codified in FDA’s regulations at 21 C.F.R. § 1271.350) are in some respects inadequate for today’s environment in which tissue products that are produced using large-scale manufacturing processes are being marketed for a wide range of applications other than mere replacement or structural/mechanical repair of damaged or diseased tissues. Currently the adverse event reporting requirements are limited to circumstances involving a communicable disease. However, these products are fully capable of causing a wider range of adverse events, similar to those that may be expected with any drug, medical device or biological product that is implanted in or applied to patients. Because FDA’s overarching mission is the protection of the public health, it is critical that FDA begin to track and collect data on these types of incidents, which may impact patients’ health even when not associated with communicable disease transmission. The requirements should be consistent with the current requirements for adverse event reporting required for medical devices, biologics and drugs.</p>

Specific Comments to the Text

Line No.	Current Text	Proposed Change	Rationale
534	<p>C8: Event Reappeared After Reintroduction. Check the box “Doesn’t Apply.”</p>	<p>Check the box “Doesn’t Apply.” Provide details of any reaction or indicate N/A.</p>	<p>This guidance as written assumes an adverse reaction can never occur with the reintroduction of an HCT/P. PDA believes a reaction is possible and there should be provision to report this information in the guidance.</p>