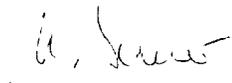




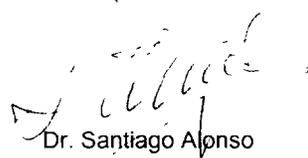
Line number(s) of draft guidance	Comments
206-208	<p>This paragraph deals only with <b>identified</b> degradation products. The current version of the guidance, however, includes a procedure for identified and unidentified impurities.</p> <p>We are of the opinion that <b>unidentified</b> impurities are also qualified if they are observed at similar levels in the innovator's drug product via a comparative study</p>
153, 213-214	<p>A clarification with regard to the term "significant metabolite" is appreciated. We propose to define every metabolite above the qualification threshold as a "significant metabolite".</p>
156-157, 224-225	<p>A clarification which kind of toxicity tests and/or argumentations are considered acceptable is appreciated.</p>
159-161	<p>To our opinion cases may arise that allow qualification of a degradation product via QSAR studies <b>and</b> conclusions by analogy for <b>structural closely related</b> compounds as such compounds often have the same degradation pathway. We are of the opinion that in these cases it is not necessary to conduct toxicity studies</p>

Sandoz appreciates the opportunity to provide feedback and suggestions to this draft guidance very much. If any questions regarding the submitted comments arise, please do not hesitate to contact us.

Yours sincerely,



Dr. Ursula Bauer  
Head QA Product Development



Dr. Santiago Alonso  
Head Global QA Sandoz