

## APS Checklist (p.1 of 4)

### First Submission (Quick Reference Checklist; See below for elaboration):

Item No	Checklist Item (Clients can use this tool to help ensure the completeness of their APS submissions)	√
1	Internally Approved	
2	Complete and Final	
3	Legible	
4	Searchable	
5	Max Occupancy = 1	
6	Format Implications (copydeck or layout)	
7	Ad content text/images	
8	Back Files Text Quoted	
9	Reference Support Copy	
10	Functionality Copy	
11	Meta-data Copy (i.e. Websites)	
12	Orientation	
13	+ Submission Letter	

### Revisions

Item No	Checklist Item (Clients can use this tool to help ensure the completeness of their submissions)	√
1	Letter	
2	Highlight revisions	
3	Format	

**\*\*NOTE:** The entire piece must be submitted for post-approval updates to the APS. It can otherwise become difficult to keep track of the APS content over time. It is not sufficient to only submit the portions which have changed.

## First Submission Checklist (p.2 of 4)

	Item No	Clarification
<b>Approved Internally</b>	1	The APS version initially submitted must be the actual version which was reviewed and <b>approved by the manufacturer's Medical, Regulatory, or Compliance staff person</b> named on the submission form. PAAB will occasionally be reaching out directly to the approval person in order to identify and discuss trends related to code infractions.
<b>Complete &amp; Final</b>	2	A "Work In Progress" (including but not limited to: multiple options for any copy, any "to-be-determined" elements, etc.) will be returned as incomplete. Significant unsolicited changes to the piece during review will require new fee (see Revisions Checklist).
<b>Legible</b>	3	Even if scanned. The format & resolution must be appropriate for screen viewing (i.e. web-quality).
<b>Searchable</b>	4	Even if scanned or in layout format, document must be text searchable (i.e. not provided in image or screen capture format). If this is not possible, a text searchable copydeck should be included within the submission.
<b>Max occupancy = 1</b>	5	Only one APS for review should be included in the submission. Separate APS for review should be separated into different submissions (e.g. downloadable PDFs, linked sites, separate pathways)
<b>Format implications</b>	6	<p>Format refers to whether the APS is initially submitted in the form of a copydeck or a layout. PAAB prefers copydecks for content review.</p> <p>If <b>only the copydeck</b> is initially submitted for content review, subsequent resubmissions must be in copydeck format. When layout is received, it will be reviewed for visual elements, positioning and formatting only (i.e. copy does not get reassessed at that time).</p> <p>In cases where <b>both a copydeck and a layout</b> are initially submitted together, the copydeck will be reviewed for content and the layout will be reviewed for visual elements, positioning and formatting only.</p> <p>If <b>only the layout</b> is submitted initially, it will be used for content review. In that case, please note that:</p> <ul style="list-style-type: none"> <li>• All subsequent resubmissions must be in layout format</li> <li>• All requirements discussed throughout this series of checklists must still be met (including but not limited to search, annotations, reference support text, and backfiles).</li> <li>• A non-annotated version may be required if annotations obscure layout and copy of the APS.</li> </ul> <p>For <b>renewals</b>, both copydeck and layout formats must be included in the initial submission if the most recently approved submission included both copydeck and layout.</p>
<b>Ad content text/images</b>	7	Content in the piece must be presented in the manner and flow in which the content is intended be presented or consumed (see functionality copy).

		All elements which appear together in final execution should appear together in copydeck/layout (e.g. graphs, images or pop-ups should not all be presented together elsewhere).
<b>Back file text quoted</b>	8	<p>PAAB file numbers from previously approved materials must be identified in close proximity to claims which are the same as (or similar to) what has been previously approved.</p> <p>This information is in a different colour from the advertising copy AND reference support copy (see below).</p>
<b>Reference support copy</b>	9	Each claim or presentation should be accompanied by clear identification of the supporting reference and the relevant page number and section of the page (e.g. ref 1A, p. 151). This referencing copy should appear in a different colour from the advertising copy. The corresponding section of the reference paper should be highlighted and labeled. This copy is referred to as “reference support copy” throughout the checklists.
<b>Functionality copy</b>	10	<p>Comprehensive and precise description of all functionalities within the piece. This applies equally to electronic tools (e.g. buttons, tabs, links...) and to print tools which have physical functionalities (e.g. pull-out rulers, folds, copy positions).</p> <p>Functionality copy and art direction notes must be clearly distinct from the APS copy.</p> <p>Information architecture and/or table of contents are required for eDetail tools and websites. Refer to guidance doc “eDetail Submissions Best Practices”.</p> <p>Indicate in the submission letter and at the top of the copy deck if the APS is representative driven vs self-directed</p>
<b>Meta-data copy (i.e. websites)</b>	11	Page title, meta descriptors, keyword metatags, ALT tags...etc. should appear on the copydeck pages they correspond to BUT they must be clearly distinct from the APS copy. <i>[Differs from SEM which must be submitted as separate file]</i>
<b>Oriented properly</b>	12	The document should open right side up.
<b>+ Submission letter</b>	13	<p>An APS must be accompanied by submission/cover letter (a separate document within the submission). It is included to provide background related to the piece.</p> <p>Some considerations:</p> <ul style="list-style-type: none"> <li>• context of use such as how it will be used (e.g. rep-directed, patient counselling)</li> <li>• what it will be used with (e.g. other tools or APS)</li> <li>• how it will be distributed (e.g. reps, mailing list, attendees)</li> <li>• anything linked to the APS in anyway</li> <li>• where is an App downloaded from (e.g. email, website, apple store)</li> <li>• special circumstances you’d like to notify the reviewer about</li> </ul>

## Revisions\*\* Checklist (p.4 of 4)

	<b>Item No</b>	<b>Clarification</b>
<b>Letter</b>	1	An itemized list of actions taken in response to PAAB comments + identify unsolicited revisions* (page # and description).  <i>*see unsolicited changes in "Highlight revisions" below</i>
<b>Highlight revisions</b>	2	Revisions made since the most recent PAAB correspondence must be highlighted on the copydeck. Highlights from prior correspondences should be removed. Ensure legibility of copy highlighted (i.e. avoid dark colours for highlighting).  For unsolicited revisions: <ul style="list-style-type: none"><li>• Identify in resubmission letter</li><li>• Identify on the piece. Highlight added elements using a different colour from the requested revisions. Removed elements are indicated by use of strikethrough in addition to the highlighting.</li><li>• Note that significant unsolicited changes will incur a new file # and fee.</li></ul>
<b>Format</b>	3	The format used for the initial submission should be maintained for the duration of content review. See format implications in APS.  Layout may be uploaded for consideration when only a copydeck was submitted on the first submission, however, it should be in addition to the copydeck, which will remain the sole source for copy review.

**\*\*NOTE:** The entire piece must be submitted for post-approval updates to the APS. It can otherwise become difficult to keep track of the APS content over time. It is not sufficient to only submit the portions which have changed.