

UNITED STATES FOOD AND DRUG ADMINISTRATION
Accreditation Scheme for Conformity Assessment Pilot Program
and Medical Device Premarket Notifications
OMB Control Nos. 0910-0889 & 0910-0120

Non-Substantive Change Request for ASCA Pilot Program Summary Test Report Format

The Food and Drug Administration is requesting a non-substantive change to support “*The Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program*” ([the ASCA Pilot](#)) and *Medical Device Premarket Notifications* (the 510(k) submission program). We believe this change request is consistent with OMB’s guidance in its flexibility memorandum of July 22, 2016 (see p.5, *Example of Use of Non-Substantive Changes for Certain Web-based or Similar Applications*).

Change to OMB Control No. 0910-0889: Under the voluntary ASCA Pilot’s conformity assessment scheme, ASCA-recognized accreditation bodies accredit testing laboratories using ISO/IEC 17025:2017: *General requirements for the competence of testing and calibration laboratories* and the ASCA program specifications associated with each FDA-recognized consensus standard and test method included in the ASCA Pilot. ASCA-accredited testing laboratories may conduct testing to determine conformance of a device with one or more of the FDA-recognized consensus standards and test methods eligible for inclusion in the ASCA Pilot. When an ASCA-accredited testing laboratory conducts testing under the ASCA Pilot, it provides to the device manufacturer all information listed in the relevant ASCA program specifications, which includes an ASCA summary test report (STR).

Currently, respondents use electronic means to fulfill information collection associated with the ASCA Pilot. No specific software, hardware, or forms are prescribed and respondents may use preferred means such as email, word processing programs, electronic filing systems to satisfy reporting and recordkeeping elements. Also, each testing laboratory may use its preferred format for STRs provided for manufacturers. (We account for this burden in *Table 3.--Estimated Annual Third-Party Disclosure Burden*, under “*Test Reports (TLs)*.”) Device manufacturers who choose to use an ASCA-accredited testing laboratory to conduct testing to support premarket submissions to FDA include a declaration of conformity (DOC) with any necessary supplemental documentation (e.g., an ASCA Pilot STR) as part of their premarket submission to FDA.

To assist respondents with the data elements we developed an electronic Submission Template And Resource ([eSTAR](#)), a fillable pdf electronic submission template that guides premarket notification (510(k)) submitters through the process of preparing a comprehensive medical device 510(k) submission. We have also finalized the associated draft instructional guidance “*The Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program*,” and have developed additional instructional guidance for respondents to the information collection. The eSTAR is not currently available for other submission types. The STR elements in eSTAR will appear when the applicant indicates an ASCA summary test report was provided for the

Cytotoxicity, Sensitization, Irritation, Acute Systemic Toxicity and Material Mediated Pyrogenicity Testing, and Hemocompatibility testing sections. We have attached a screen-capture showing the specific data elements that would be included, using the *Cytotoxicity* section as an example. Manufacturers using eSTAR to prepare their 510(k) submission may enter the STR information directly into eSTAR as they prepare their submission.

We also leveraged eSTAR to create a pdf version of the STR format, which includes the *Biocompatibility* section of eSTAR, which includes all of the sections mentioned above, and the ASCA Pilot STR data elements, to be used by ASCA-accredited testing laboratories that submit STRs to manufacturers; manufacturers that provide STR information, but do not use eSTAR to prepare their 510(k) submission (or who choose to upload the STR pdf format into eSTAR); and manufacturers that provide STR information in other types of premarket submission.

We expect that the standardized format to simplify ASCA-accredited testing laboratories' provision of STRs to manufacturers, and in turn, may also simplify manufacturers' inclusion of the STR information in premarket applications. We have made no adjustment to our burden estimates but hope to see increased functionality with internal tools used by our staff, and we also hope to see improved operational efficiencies.

Change to OMB Control No. 0910-0120: We also request to utilize eSTAR for summary test reports and data elements submitted by manufacturers in their premarket submissions. Again, eSTAR is not currently available for other submission types. We have made no adjustment to our currently approved burden estimate, but hope to see improved operational efficiencies in reviewing Premarket Notifications.

Dated: September 2021