COMMENT ON DOCKET NO. FDA-2026-N-7130

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Agency Information Collection Activities; Proposed Collection; Comment Request; Accreditation Scheme for Conformity Assessment Program OMB Control Number 0910-0889

I am a patient. I carry a five-level cervical fusion, which is an implanted orthopedic device with a bone contacting surface. I also had a hip prosthesis, which was removed in a resection arthroplasty in October 2017 and not replaced. I address topic (1), whether the information collected has practical utility, and topic (3), ways to enhance its quality, utility and clarity.

Nine years after section 514(d) of the Federal Food, Drug, and Cosmetic Act was added by the FDA Reauthorization Act of 2017, the program operates in two standards families, and the surface that touches bone in a permanently implanted device is in neither.

Topic (1). The collection gathers applications, scope requests and status reports from accreditation bodies and testing laboratories. For each participant, FDA records a scope of recognition identifying the specific standards and test methods to which it may accredit or test. That record's value depends on how far the program reaches.

FDA's ASCA-Accredited Testing Laboratories database, read on September 8 2026, the page last updated on September 7, 2026, lists 98 laboratories. Every one is recorded in a single ASCA category, either Basic safety and essential performance or Biocompatibility. No laboratory appears in any category covering mechanical testing, materials characterization, or implant surface and coating assessment.

Of the 98, 5 are recorded under Biocompatibility, being North American Science Associates, Nelson Laboratories, WuXi AppTec Suzhou, Eurofins Biolab Srl and Product Safety Labs. The remaining 93 are recorded under Basic safety and essential performance. The two categories account for the entire program.

On July 28, 2025 the Division of Standards and Conformity Assessment fully recognized IEC 61326-2-6 Edition 4, and the page states that the standard is part of the family under IEC 61010 and within the scope of the ASCA Basic Safety and Essential Performance standards-specific guidance. The addition sits inside one of the two existing families.

That is the agency's description. FDA's ASCA page states the program includes cross-cutting and device-specific standards, the agency chose standards and tests from the biocompatibility and basic safety and essential performance series, and manufacturers should continue to rely on other recognized standards and provide declarations of

conformity, but other standards will not be eligible for the benefits of ASCA. I am not disputing that scope decision. I am pointing out what follows from it for this collection.

My concern is what the collection can tell FDA. A collection that captures scopes of accreditation inside a two-category program produces a dataset that says nothing about where accredited testing would be useful next, because it asks nothing about the areas the program does not reach.

Topic (3). The notice records that the feedback questionnaire now includes device manufacturers as respondents alongside accreditation bodies and testing laboratories, at 158 respondents and 30 minutes each, with the respondent count and hours unchanged. That instrument is approved and in use, and it already reaches all three classes of participant.

I suggest it add additional items. First, ask each respondent which FDA-recognized consensus standards or test methods outside the current ASCA categories they would use an accredited laboratory for, were the program extended. One question inside an existing 30-minute instrument adds no respondent and no response. It would give FDA an evidence base for deciding where the next scope should go. As the questionnaire stands, the collection can report only on the areas it already covers.

Second, ask whether the respondent considers the information generated under the program to be available to, and usable by, a clinician or a patient reviewing a device after implantation. The three respondent classes are the parties who take part in the program commercially. None of them is the person the assessed device is placed into. I am not asking that patients be added as respondents, which would change the burden this notice asks about. I am asking that the respondents you already have be asked the question.

The one other comment on this docket, submitted September 1, 2026 by the American Association for Laboratory Accreditation, addresses the process by which an already recognized accreditation body extends its ASCA recognition to additional FDA-recognized consensus standards or test methods. A2LA reports that it accredits approximately 60 laboratories in the program and asks that the extension process be simplified, so that a body seeking to add standards need submit only what is directly relevant to the requested extension and what has materially changed since its last renewal. Extension is the mechanism by which any new standard enters ASCA. A2LA describes that mechanism as administratively burdensome. This comment observes that in nine years it has not reached mechanical testing, materials characterization, or implant surface and coating assessment. The two questionnaire items proposed here would tell FDA which extensions are worth the burden.

And the agency's most recent notice bears on practical utility. The ASCA-Accredited Testing Laboratories page carries an update dated September 18, 2025 recording that the agency has noted the withdrawal of ASCA accreditation for certain laboratories, those laboratories are listed with an FDA Initiated Withdrawal status, and ASCA Summary Test Reports from them will no longer be accepted. The stated reason is that during audits the agency determined the laboratories did not meet the requirements outlined in section 514(d) and related ASCA program guidance, in some cases it identified concerns about the integrity of

the data the laboratories submitted in premarket submissions, and these findings raised serious questions about the ability of certain laboratories to fulfill their role in the program.

The collection records each participant's scope of recognition. It does not, on the face of the notice, record what an audit found, or what a withdrawal was based on, in a form that can be counted or compared. A collection whose purpose is to support the program's administration has more practical utility if it captures the outcome of the audits the agency is already conducting, not only the scopes it grants. That is a question about the fields collected, which is what this notice asks about.

For devices inside ASCA, FDA states that it does not intend to request additional information regarding testing methodologies. For devices outside it, including orthopedic implants with coated bone-contacting surfaces, there is no accredited-laboratory record to request. What sits in the public file in both cases is a declaration.

The limits of a declaration are visible in FDA's recognition records. ISO 13779-2 Third edition 2018-12, recognition number 8-493, entered July 15, 2019, is recognized as a complete standard for thermally sprayed hydroxyapatite coatings. The scope FDA reproduces states that the document specifies requirements for single layer coatings. Its NOTE 2 records that the requirements for the hydroxyapatite layer of dual-layer coatings, consisting of a lower layer of metallic coating and an upper layer of hydroxyapatite coating, can follow the document, but that the testing methods referred to in it cannot be applied to dual layer coatings, and that a rationale on how single-layer tested coupons are representative of the dual-layer coated implant might be considered necessary. Many orthopedic implants carry multi-layer coatings, and the one that was placed in me is described in the manufacturer's own submissions as hydroxyapatite over a porous titanium coating, a description that omits the metal grit-blast deposition between them. A declaration naming that standard therefore leaves open which layer was assessed and whether such a rationale was prepared.

I raise this to show the kind of gap the two questionnaire items would surface, not to ask that this standard be brought into ASCA, which is a policy question outside a Paperwork Reduction Act notice. I have read the clearance record for the device that was implanted in me and for the devices it was cleared against, and it tells a later reader almost nothing about the surface of that device. Two questions in a questionnaire you already send would start to show FDA whether that is a gap worth closing.

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