

responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

- (1) Is not a “significant regulatory action” under Executive Order 12866,
- (2) Is not a “significant rule” under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),
- (3) Will not affect intrastate aviation in Alaska, and
- (4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

**List of Subjects in 14 CFR Part 39**

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

**The Proposed Amendment**

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

**PART 39—AIRWORTHINESS DIRECTIVES**

■ 1. The authority citation for part 39 continues to read as follows:

**Authority:** 49 U.S.C. 106(g), 40113, 44701.

**§ 39.13 [Amended]**

■ 2. The FAA amends § 39.13 by adding the following new AD:

**GROB-WERKE:** Docket No. FAA–2014–0092; Directorate Identifier 2014–CE–002–AD.

**(a) Comments Due Date**

We must receive comments by April 7, 2014.

**(b) Affected ADs**

None.

**(c) Applicability**

This AD applies to GROB-WERKE Model G115E airplanes, all serial numbers, and Model G120A airplanes, serial numbers 85001 through 85007, 85026 through 85056, and 85058, certificated in any category.

**(d) Subject**

Air Transport Association of America (ATA) Code 55: Stabilizers.

**(e) Reason**

This AD was prompted by mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as cracks in the left hand elevator flange. We are issuing this AD to detect and correct cracks in the left hand and right hand elevator flanges, which could cause the elevator to fail and could result in reduced control.

**(f) Actions and Compliance**

Unless already done, do the actions in paragraphs (f)(1) through (f)(3) of this AD:

(1) Within the next 30 days after the effective date of this AD and repetitively thereafter at intervals not to exceed 100 hours time-in-service (TIS), inspect the left hand (LH) and the right hand (RH) elevator flanges, part number (P/N) 115E–3761.06 and P/N 115E–3762.07, or P/N 120A–3561.20(A) and P/N 120A–3562.20(A), as applicable, for cracks. Do the inspections following GROB Aircraft Service Bulletin No. MSB1078–194/1, dated December 3, 2013, or GROB Aircraft Service Bulletin No. MSB1121–140, dated December 3, 2013, as applicable.

(2) If any crack is found during any inspection required in paragraph (f)(1) of this AD, before further flight, replace the affected elevator flange with a serviceable part. Do the replacement following GROB Aircraft Service Bulletin No. MSB1078–194/1, dated December 3, 2013, or GROB Aircraft Service Bulletin No. MSB1121–140, dated December 3, 2013, as applicable.

(3) As of the effective date of this AD, only install an elevator flange P/N 115E–3761.06, P/N 115E–3762.07, P/N 120A–3561.20(A), or P/N 120A–3562.20(A), if it has been inspected following GROB Aircraft Service Bulletin No. MSB1078–194/1, dated December 3, 2013, or GROB Aircraft Service Bulletin No. MSB1121–140, dated December 3, 2013, as applicable, and is free of any cracks.

**(g) Credit for Actions Accomplished in Accordance With Previous Service Information for Model G115E Airplanes**

This paragraph provides credit for the initial inspection required in paragraph (f)(1) of this AD and any replacement required in paragraph (f)(2) based on the result of the initial inspection if already done before the effective date of this AD following GROB Aircraft Service Bulletin No. MSB1078–194, dated November 26, 2013.

**(h) Other FAA AD Provisions**

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Standards Office, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Karl Schletzbaum, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4123; fax: (816) 329–4090; email: [karl.schletzbaum@faa.gov](mailto:karl.schletzbaum@faa.gov). Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(2) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(3) *Reporting Requirements:* For any reporting requirement in this AD, a federal

agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2120–0056. Public reporting for this collection of information is estimated to be approximately 5 minutes per response, including the time for reviewing instructions, completing and reviewing the collection of information. All responses to this collection of information are mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at: 800 Independence Ave. SW., Washington, DC 20591, Attn: Information Collection Clearance Officer, AES–200.

**(i) Related Information**

Refer to MCAI European Aviation Safety Agency (EASA) AD No. 2014–0004, dated January 7, 2014; and GROB Aircraft Service Bulletin No. MSB1078–194, dated November 26, 2013, for related information. You may examine the MCAI on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA–2014–0092. For service information related to this AD, contact Grob Aircraft AG, Customer Service, Lettenbachstrasse 9, 86874 Tussenhausen-Mattsies, Germany, telephone: + 49 (0) 8268–998–105; fax: + 49 (0) 8268–998–200; email: [productsupport@grob-aircraft.com](mailto:productsupport@grob-aircraft.com); Internet: [grob-aircraft.com](http://grob-aircraft.com). You may review this referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Issued in Kansas City, Missouri, on February 11, 2014.

**Earl Lawrence,**

*Manager, Small Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 2014–03606 Filed 2–19–14; 8:45 am]

**BILLING CODE 4910–13–P**

**SOCIAL SECURITY ADMINISTRATION**

**20 CFR Parts 404, 405, and 416**

[Docket No. SSA–2012–0068]

**RIN 0960–AH53**

**Submission of Evidence in Disability Claims**

**AGENCY:** Social Security Administration.

**ACTION:** Notice of proposed rulemaking (NPRM).

**SUMMARY:** We propose to clarify our regulations to require you to inform us about or submit all evidence known to you that relates to your disability claim, subject to two exceptions for certain privileged communications. This

requirement would include the duty to submit all evidence obtained from any source in its entirety, unless subject to one of these exceptions. We also propose to require your representative to help you obtain the information or evidence that we would require you to submit under our regulations. These modifications to our regulations would better describe your duty to submit all evidence that relates to your disability claim and enable us to have a more complete case record on which to make more accurate disability determinations and decisions.

**DATES:** To ensure that your comments are considered, we must receive them by no later than April 21, 2014.

**ADDRESSES:** You may submit comments by any one of three methods—Internet, fax, or mail. Do not submit the same comments multiple times or by more than one method. Regardless of which method you choose, please state that your comments refer to Docket No. SSA–2012–0068 so that we may associate your comments with the correct regulation.

*Caution:* You should be careful to include in your comments only information that you wish to make publicly available. We strongly urge you not to include in your comments any personal information, such as Social Security numbers or medical information.

1. *Internet:* We strongly recommend this method for submitting your comments. Visit the Federal eRulemaking portal at <http://www.regulations.gov>. Use the Web page's *Search* function to find docket number SSA–2012–0068 and then submit your comment. Once you submit your comment, the system will issue you a tracking number to confirm your submission. You will not be able to view your comment immediately because we must manually post each comment. It may take up to a week for your comment to be viewable.

2. *Fax:* Fax comments to (410) 966–2830.

3. *Mail:* Address your comments to the Office of Regulations and Reports Clearance, Social Security Administration, 3100 West High Rise Building, 6401 Security Boulevard, Baltimore, Maryland 21235–6401.

Comments are available for public viewing on the Federal eRulemaking portal at <http://www.regulations.gov> or in person, during regular business hours, by arranging with the contact person identified below.

**FOR FURTHER INFORMATION CONTACT:** Janet Truhe, Office of Disability Programs, Social Security

Administration, 6401 Security Boulevard, Baltimore, Maryland 21235–6401, (410) 966–7203. For information on eligibility or filing for benefits, call our national toll-free number, 1–800–772–1213, or TTY 1–800–325–0778, or visit our Internet site, Social Security Online, at <http://www.socialsecurity.gov>.

#### SUPPLEMENTARY INFORMATION:

##### Background

The Social Security Act (Act) gives the Commissioner of Social Security broad rulemaking authority to issue regulations governing the production of evidence that we use to adjudicate disability claims under title II and title XVI.<sup>1</sup> Additionally, the Act provides that we will not find that an individual is disabled “unless [he or she] furnishes such medical and other evidence of the existence thereof as the Commissioner of Social Security may require.”<sup>2</sup>

There has been recent public and media interest in what our regulations require regarding the submission of evidence in disability claims, particularly regarding the duty to submit unfavorable evidence. There have been allegations that when some representatives submit evidence to us, they deliberately withhold evidence they deem unfavorable to the claimant. We also know, based on our program experience, that we do not always receive complete evidence. This public and media interest has drawn congressional attention.<sup>3</sup> In particular, members of Congress have asked about the relationship between the Social Security Protection Act of 2004 (SSPA) and the duty to submit potentially unfavorable evidence in disability claims. The SSPA authorized us to penalize a person who withholds a fact, which the person knows or should

know is material to the determination of any initial or continuing right to benefits. In light of congressional interest and our program experience, we have again reviewed our regulations that govern the submission of evidence.

Our current regulations describe a claimant's duty to submit medical and non-medical evidence in several ways. For example, in § 404.1512(a), we state that you “must bring to our attention everything that shows that you are blind or disabled,” which may only include evidence that is favorable to your claim.<sup>4</sup> In §§ 404.1512(c) and 416.912(c), however, we state that you “must provide evidence, without redaction, showing how your impairment(s) affects your functioning during the time you say that you are disabled,” which may include evidence that is unfavorable to your claim. Similarly, our current regulations governing the conduct of claimants' representatives describe their related duty to submit evidence in several ways. For example, in §§ 404.1740(b)(1) and 416.1540(b)(1), we require representatives to “obtain the information and evidence that the claimant wants to submit in support of his or her claim,” which may only include evidence that is favorable to the disability claim. In §§ 404.1740(b)(2) and 416.1540(b)(2), however, we require representatives to assist the claimant in complying “with our requests for information or evidence,” which may include evidence that is unfavorable to the claim.

In reviewing our regulations on the submission of evidence, we also considered Congress' actions in enacting the SSPA. When it enacted the SSPA, Congress authorized us to impose a civil monetary penalty against any person who omits from a statement or representation or otherwise withholds disclosure of a fact that is material to the determination of any initial or continuing right to benefits or payments, if the person knows or should know that omitting or withholding the fact is misleading.<sup>5</sup> The sheer volume of disability claims we decide each year makes the need for a complete case record imperative. In fiscal year 2012, for example, we completed more than 3.2 million initial disability claims and more than 820,000 hearing requests.<sup>6</sup> Clarifying our rules regarding a claimant's duty to submit all

<sup>1</sup> See 42 U.S.C. 405(a) and 1383(d)(1).

<sup>2</sup> 42 U.S.C. 423(d)(5)(A). See also 42 U.S.C. 1382c(a)(3)(H)(i) (making the provisions of section 423(d)(5) applicable under title XVI).

<sup>3</sup> See, e.g., The Social Security Administration: Is It Meeting Its Responsibility to Save Taxpayer Dollars and Serve the Public?: Hearing Before the S. Comm. on Finance, 112th Cong. 18–19, 52–54 (2012), available at <http://www.finance.senate.gov/hearings/hearing/?id=35b30665-5056-a032-52b7-89db5b56d235>; Fourth in a Hearing Series on Securing the Future of the Social Security Disability Insurance Program: Hearing Before the Subcomm. on Social Security of the H. Comm. on Ways and Means, 112th Cong. (2012), available at <http://waysandmeans.house.gov/news/documentsingle.aspx?DocumentID=326594>; Minority Staff Report, S. Perm. Subcomm. on Investigations, Social Security Disability Programs: Improving the Quality of Benefit Award Decisions 5–6 (2012), available at <http://www.hsgac.senate.gov/download/report-psi-minority-staff-report-social-security-disability-programs-improving-the-quality-of-benefit-award-decisions>.

<sup>4</sup> See also 20 CFR 416.912(a).

<sup>5</sup> Social Security Protection Act of 2004, § 201, 42 U.S.C. 1320a–8.

<sup>6</sup> Social Security Administration, *Performance and Accountability Report, Fiscal Year 2012*, at 56, 62, available at <http://www.socialsecurity.gov/finance/2012/Full%20FY%202012%20PAR.pdf>.

evidence that relates to the disability claim would enable us to obtain more complete case records and adjudicate claims more accurately.

As part of our reevaluation of the regulations governing the duty to submit evidence in disability claims, we also consulted with the Administrative Conference of the United States (ACUS)<sup>7</sup> and requested recommendations on how our regulations could better articulate the duty to submit all evidence that relates to the disability claim. ACUS issued its Final Report in October 2012.<sup>8</sup> Although the particular content of any regulation was beyond the scope of ACUS's Final Report, ACUS did identify several principles and options that have guided our efforts in this area.

First, ACUS recommended that any proposed regulation should place disclosure obligations directly on claimants rather than on their representatives (if any), just as Federal courts place discovery and other evidence-production obligations on civil litigants, not their counsel. Second, ACUS recommended that any proposed disclosure obligations should apply both to attorney and non-attorney representatives. Third, ACUS recommended that we should write any disclosure obligations so that they do not intrude on any established legal privileges, including the attorney-client privilege or (assuming it is applicable in this context) the work-product doctrine. The obligations should not, among other things, require a claimant (or his or her representative) to disclose his or her subjective opinions regarding the evidence. Finally, ACUS recommended that we should write any disclosure obligations in a way that would minimize the extent to which a claimant and his or her representative must make subjective judgments as to the legal relevance of particular evidence. We now propose to clarify our regulations regarding the submission of evidence, based in part on the recommendations and principles in ACUS's Final Report and mindful of the concerns that prompted Congress to amend section

<sup>7</sup> ACUS is "an independent federal agency dedicated to improving the administrative process through consensus-driven applied research, providing nonpartisan expert advice and recommendations for improvement of federal agency procedures." About the Administrative Conference of the United States (ACUS), available at <http://www.acus.gov/about-administrative-conference-united-states-acus>.

<sup>8</sup> Administrative Conference of the United States, *SSA Disability Benefits Programs: The Duty of Candor and Submission of All Evidence* (Oct. 15, 2012) ("ACUS Final Report"), available at [http://www.acus.gov/sites/default/files/documents/ACUS\\_Final\\_Report\\_SSA\\_Duty\\_of\\_Candor.pdf](http://www.acus.gov/sites/default/files/documents/ACUS_Final_Report_SSA_Duty_of_Candor.pdf).

1129 of the Act, 42 U.S.C. 1320a–8, as part of the SSPA. The modifications we propose to our regulations will provide more certainty about the duty to submit all evidence that relates to disability claims.

### Proposed Changes

#### *The Claimant's Duty To Submit Evidence*

We propose to revise §§ 404.1512(a) and 416.912(a) to require you to inform us about or submit all evidence known to you that relates to whether or not you are blind or disabled.<sup>9</sup> This would include evidence that may be either favorable or unfavorable to your claim. As part of this proposal, we would remove our current requirement in sections 404.1512(a) and 416.912(a) that you "must furnish medical and other evidence that we can use to reach conclusions about your medical impairment(s)." The duty to inform us about or submit all evidence that relates to your disability claim would include all of the types of evidence we need to determine disability under our regulations and would remove the need for you to determine what evidence is "material" to the disability determination. In addition, by requiring you to inform us about or submit all evidence that relates to your disability claim, we would clarify that we are not shifting our responsibility for developing the record to you. Our disability system is non-adversarial, and we assist claimants in developing the medical and non-medical evidence we need to determine whether or not they are disabled.<sup>10</sup>

We also propose to add a new paragraph to current §§ 404.1512(b) and 416.912(b), which would set forth two exceptions to what we mean by

<sup>9</sup> Under the Act, a claimant must prove to us that he or she is blind or disabled. 42 U.S.C. 423(d)(5)(A) and 1382c(a)(3)(H)(i). A claimant is disabled only if he or she is unable to do any substantial gainful activity because he or she has a medically determinable impairment that can be expected to result in death or which has lasted or can be expected to last for a period of at least 12 continuous months. 42 U.S.C. 423(d)(1)(A) and 1382c(3)(A). To be found disabled, a claimant must also be both "unable to do [his or her] previous work" and unable to do "any other kind of substantial gainful work which exists in the national economy." 42 U.S.C. 423(d)(2)(A) and 1382c(a)(3)(B).

<sup>10</sup> For example, consistent with our duty under the Act, we must develop a claimant's "complete medical history," generally for at least the 12 months preceding the application date. 42 U.S.C. 423(d)(5)(B) and 1382c(a)(3)(H)(i); 20 CFR 404.1512(d) and 416.912(d). In addition, at the hearings level, administrative law judges have a duty "to investigate the facts and develop the arguments both for and against granting benefits." *Sims v. Apfel*, 530 U.S. 103, 111 (2000).

"evidence."<sup>11</sup> First, in proposed §§ 404.1512(b)(2)(i) and 416.912(b)(2)(i), we would exclude oral and written communications between you and your representative that are subject to the attorney-client privilege, unless you voluntarily disclose the communication to us. The attorney-client privilege protects confidential communications between a client and his or her attorney in order to obtain and provide sound legal assistance.<sup>12</sup> Its purpose is to encourage attorneys and their clients to communicate fully and frankly.<sup>13</sup> This privilege does not apply to communications with non-attorney representatives, but we would also exclude from the definition of evidence communications between claimants and their non-attorney representatives that would be subject to the attorney-client privilege, if the non-attorney representative were an attorney. As recommended by ACUS in its Final Report, we believe that any proposed disclosure obligations "should apply both to attorney and non-attorney representatives."<sup>14</sup>

The attorney-client privilege "only protects disclosure of communications; it does not protect disclosure of the underlying facts by those who communicated with the attorney."<sup>15</sup> For example, if you write a letter to your representative disclosing the names of your medical source(s), the privilege would preclude disclosure of the letter, but not the names of your medical source(s).

Second, in proposed §§ 404.1512(b)(2)(ii) and 416.912(b)(2)(ii), we propose to exclude your representative's analysis of your claim, unless he or she voluntarily discloses it to us. By "analysis of your

<sup>11</sup> We describe what we mean by "evidence" in current §§ 404.1512(b)(1)–(8) and 416.912(b)(1)–(8) (proposed sections 404.1512(b)(1)(i)–(viii), 416.912(b)(1)(i)–(viii)). We do not propose any changes to these sections other than to add the phrase "and other program physicians, psychologists, or other medical specialists" to current §§ 404.1512(b)(6) and 416.912(b)(6) (proposed sections 404.1512(b)(1)(vi), 416.912(b)(1)(vi)) in conformity with the cross-references that appear in these sections. We inadvertently omitted this phrase when we last revised these sections.

<sup>12</sup> See *Upjohn v. United States*, 449 U.S. 383, 389 (1981).

<sup>13</sup> *Id.*

<sup>14</sup> ACUS Final Report at 38. ACUS made this recommendation after consulting with the National Organization of Social Security Claimants' Representatives and the National Association of Disability Representatives (whose members also include non-attorney representatives). Both of these advocate groups recommended that any proposed changes to our evidence regulations apply to all claimant representatives without distinction between attorneys and non-attorneys. *Id.* at A–5 and A–8.

<sup>15</sup> *Upjohn*, 449 U.S. at 395.

claim,” we generally mean the information that is subject to the attorney work product doctrine.<sup>16</sup> This doctrine protects an attorney’s analysis, theories, mental impressions, and notes.<sup>17</sup> Its purpose is to provide an attorney with a degree of privacy within which to carefully and thoroughly prepare his or her client’s case.<sup>18</sup>

We do not intend, however, to incorporate into these proposed rules the full scope of the work product doctrine under Rule 26(b) of the Federal Rules of Civil Procedure. Rather, consistent with our broad authority under the Act to “adopt reasonable and proper rules and regulations to regulate and provide for the nature and extent of the proofs and evidence and the method of taking and furnishing the same in order to establish the right to benefits,”<sup>19</sup> these proposed rules incorporate a more limited version of the work product doctrine than would apply under the Federal Rules. Under these proposed rules, your representative’s “analysis of your claim” does not include certain material that we may consider in determining whether or not you are entitled to or eligible for the benefits for which you have applied. For example, if your representative takes notes during a discussion with one of your medical sources about your condition, we would consider those notes your representative’s analysis of your claim, and they would be protected from disclosure under these proposed rules. However, if your medical source sends your representative medical records or a written opinion about your condition, your representative could not withhold those records and that opinion based on the work product doctrine. Those documents would be subject to the duty of disclosure under these proposed rules.

To clarify this point, we provide in proposed §§ 404.1512(b)(2)(ii) and 416.912(b)(2)(ii) that your representative’s “analysis of your claim” means information that is subject to the attorney work product doctrine, but does not include medical evidence, medical source opinions, or any other factual matter that we may consider in determining whether or not you are entitled to or eligible for benefits. We

then provide a cross-reference to new paragraph (b)(2)(iv), where we further explain the scope of the privileges within the context of these proposed rules.

Although the work product doctrine applies only to attorneys, we also exclude from the definition of evidence documents that would be subject to the work product privilege, if the non-attorney representative were an attorney, to the same extent that we have discussed above.

We also propose revising §§ 404.1512(c) and 416.912(c) to clarify that it is *your* responsibility to inform us about or submit all evidence known to you that relates to whether or not you are blind or disabled.<sup>20</sup> In addition, when you submit evidence to us from another source, we would require you in proposed §§ 404.1512(c) and 416.912(c) to submit that evidence in its entirety. For example, if you obtain your patient file from one of your medical sources, we would require you to submit *all* of the medical records in that file. When we last revised §§ 404.1512(c) and 416.912(c) to require that you provide evidence “without redaction,” we explained at the time that this means, for example, you must not redact evidence from a medical report you submit to us.<sup>21</sup> As ACUS pointed out in its Final Report, however, we did not define “without redaction” or fully explain what we meant by this requirement.<sup>22</sup> Therefore, one could interpret “without redaction” to mean either within a document or among a group of documents.<sup>23</sup> We intend our proposed requirement for submission of evidence in its entirety to clarify that we mean both types of redaction.

Finally, in proposed §§ 404.1512(c)(1) and 416.912(c)(1), we would clarify that, if we ask you, you must inform us about your medical source(s). We currently request the names and addresses of all of your medical source(s) on the adult and child disability applications;<sup>24</sup> such information is within the scope of your current responsibility to submit evidence that shows you are blind or disabled.<sup>25</sup> However, as part of our clarification of your duty to inform us

<sup>20</sup> In so doing, we would place the disclosure obligation directly on claimants rather than on their representatives “just as discovery and other evidence-production obligations in federal courts are placed on civil litigants, not their counsel.” ACUS Final Report at 38.

<sup>21</sup> See 71 FR 16424, 16437 (2006).

<sup>22</sup> See ACUS Final Report at 7.

<sup>23</sup> *Id.*

<sup>24</sup> These are the Form SSA–3368–BK, Disability Report—Adult and the Form SSA–3820–BK, Disability Report—Child.

<sup>25</sup> See §§ 404.1512(a) and (c) and 416.912(a) and (c).

about or submit all evidence that relates to your disability claim, we believe we should expressly list this type of evidence with the other types referenced in current §§ 404.1512(c)(1)–(6) and 416.912(c)(1)–(6).

#### *The Representative’s Duty To Submit Evidence*

As stated above, we propose to place the duty to submit evidence directly on claimants, not their representatives, if represented. Therefore, we propose to revise §§ 404.1740(b)(1) and 416.1540(b)(1) to require that representatives help obtain the information or evidence that claimants must submit under our proposed regulations. By requiring representatives to help obtain the information or evidence that claimants must submit, we would clarify that we are not shifting our responsibility to develop the record to claimants’ representatives.

#### **Other Changes**

We propose to make a number of other non-substantive changes to the current rules. We are proposing these changes for clarity and consistency and to correct minor grammatical errors. For example, we propose to revise some language from passive to active voice. We would also make conforming changes to §§ 404.900, 405.1, and 416.1400, which introduce and explain the nature of the administrative review process, and §§ 404.935, 405.331, and 416.1435, which pertain to a claimant’s duty to submit evidence at the hearings level.

#### **Clarity of This Proposed Rule**

Executive Order 12866, as supplemented by Executive Order 13563, requires each agency to write all rules in plain language. In addition to your substantive comments on this proposed rule, we invite your comments on how to make it easier to understand.

For example:

- Would more, but shorter, sections be better?
- Are the requirements in the rule clearly stated?
  - Have we organized the material to suit your needs?
  - Could we improve clarity by adding tables, lists, or diagrams?
  - What else could we do to make the rule easier to understand?
- Does the rule contain technical language or jargon that is not clear?
- Would a different format make the rule easier to understand, e.g., grouping and order of sections, use of headings, paragraphing?

<sup>16</sup> See *Hickman v. Taylor*, 329 U.S. 495, 510–12 (1947).

<sup>17</sup> *Id.* at 511.

<sup>18</sup> *Id.* at 510–11.

<sup>19</sup> 42 U.S.C. 405(a) and 1383(d)(1); see *Heckler v. Campbell*, 461 U.S. 458, 466 (1983) (recognizing the Commissioner’s “exceptionally broad authority” under section 405(a) “to prescribe standards for applying certain sections of the [Social Security] Act.” (Alteration in original)).

**When will we start to use this rule?**

We will not use this rule until we evaluate public comments and publish a final rule in the **Federal Register**. All final rules we issue include an effective date. We will continue to use our current rules until that date. If we publish a final rule, we will include a summary of relevant comments we received, responses to them, and an explanation of how we will apply the new rule.

**Regulatory Procedures**

*Executive Order 12866, as Supplemented by Executive Order 13563*

We consulted with the Office of Management and Budget (OMB) and determined that this proposed rule meets the criteria for a significant regulatory action under Executive Order 12866, as supplemented by Executive Order 13563. Therefore, OMB reviewed it.

*Regulatory Flexibility Act*

We certify that this proposed rule would not have a significant economic impact on a substantial number of small entities because it affects individuals only. Therefore, a regulatory flexibility analysis is not required under the Regulatory Flexibility Act, as amended.

*Paperwork Reduction Act*

This NPRM imposes no reporting or recordkeeping requirements subject to OMB clearance.

**References**

We consulted the references cited in the footnotes when we developed these proposed rules. We included these references in the rulemaking record for these proposed rules and will make them available for inspection by interested individuals who make arrangements with the contact person identified above.

(Catalog of Federal Domestic Assistance Program Nos. 96.001, Social Security—Disability Insurance; 96.002, Social Security—Retirement Insurance; and 96.004, Social Security—Survivors Insurance)

**List of Subjects***20 CFR Part 404*

Administrative practice and procedure, Blind, Disability benefits, Old-Age, Survivors, and Disability insurance, Reporting and recordkeeping requirements, Social Security.

*20 CFR Part 405*

Administrative practice and procedure, Blind, Disability benefits, Old-Age, Survivors, and Disability

insurance, Public assistance programs, Reporting and recordkeeping requirements, Social Security, Supplemental Security Income (SSI).

*20 CFR Part 416*

Administrative practice and procedure, Aged, Blind, Disability benefits, Public assistance programs, Reporting and recordkeeping requirements, Supplemental Security Income (SSI).

Dated: February 11, 2014.

**Carolyn W. Colvin,**

*Acting Commissioner of Social Security.*

For the reasons stated in the preamble, we propose to amend subparts J, P, and R of part 404, subparts A and D of part 405, and subparts I, N, and O of part 416 as set forth below:

**PART 404—FEDERAL OLD-AGE, SURVIVORS AND DISABILITY INSURANCE (1950- )****Subpart J—[Amended]**

■ 1. The authority citation for subpart J of part 404 continues to read as follows:

**Authority:** Secs. 201(j), 204(f), 205(a)–(b), (d)–(h), and (j), 221, 223(i), 225, and 702(a)(5) of the Social Security Act (42 U.S.C. 401(j), 404(f), 405(a)–(b), (d)–(h), and (j), 421, 423(i), 425, and 902(a)(5)); sec. 5, Pub. L. 97–455, 96 Stat. 2500 (42 U.S.C. 405 note); secs. 5, 6(c)–(e), and 15, Pub. L. 98–460, 98 Stat. 1802 (42 U.S.C. 421 note); sec. 202, Pub. L. 108–203, 118 Stat. 509 (42 U.S.C. 902 note).

■ 2. Amend § 404.900 by revising paragraph (b) to read as follows:

**§ 404.900 Introduction**

\* \* \* \* \*

(b) *Nature of the administrative review process.* In making a determination or decision in your case, we conduct the administrative review process in an informal, non-adversarial manner. Subject to the limitations on Appeals Council consideration of additional evidence (*see* §§ 404.970(b) and 404.976(b)), we will consider at each step of the review process any information you present as well as all the information in our records. You may present the information yourself or have someone represent you, including an attorney. If you are dissatisfied with our decision in the review process, but do not take the next step within the stated time period, you will lose your right to further administrative review and your right to judicial review, unless you can show us that there was good cause for your failure to make a timely request for review.

\* \* \* \* \*

■ 3. Revise § 404.935 to read as follows:

**§ 404.935 Submitting evidence prior to a hearing before an administrative law judge.**

You should submit information or evidence as required by § 404.1512 or any summary of the evidence to the administrative law judge with the request for hearing or within 10 days after filing the request, if possible. Each party shall make every effort to ensure that the administrative law judge receives all of the evidence (*see* § 404.1512) or all of the evidence is available at the time and place set for the hearing.

**Subpart P—[Amended]**

■ 4. The authority citation for subpart P of part 404 continues to read as follows:

**Authority:** Secs. 202, 205(a)–(b) and (d)–(h), 216(i), 221(a), (i), and (j), 222(c), 223, 225, and 702(a)(5) of the Social Security Act (42 U.S.C. 402, 405(a)–(b) and (d)–(h), 416(i), 421(a), (i), and (j), 422(c), 423, 425, and 902(a)(5)); sec. 211(b), Pub. L. 104–193, 110 Stat. 2105, 2189; sec. 202, Pub. L. 108–203, 118 Stat. 509 (42 U.S.C. 902 note).

■ 5. In § 404.1512, revise paragraphs (a) through (c) to read as follows:

**§ 404.1512 Evidence.**

(a) *General.* In general, you have to prove to us that you are blind or disabled. You must inform us about or submit all evidence known to you that relates to whether or not you are blind or disabled. We will consider only impairment(s) you say you have or about which we receive evidence.

(b) *What we mean by “evidence.”* Evidence is anything you or anyone else submits to us or that we obtain that relates to your claim.

(1) Evidence includes, but is not limited to:

(i) Objective medical evidence, that is, medical signs and laboratory findings as defined in § 404.1528(b) and (c);

(ii) Other evidence from medical sources, such as medical history, opinions, and statements about treatment you have received;

(iii) Statements you or others make about your impairment(s), your restrictions, your daily activities, your efforts to work, or any other statements you make to medical sources during the course of examination or treatment, or to us during interviews, on applications, in letters, and in testimony in our administrative proceedings;

(iv) Information from other sources, as described in § 404.1513(d);

(v) Decisions by any governmental or nongovernmental agency about whether or not you are disabled or blind (*see* § 404.1504);

(vi) At the initial level of the administrative review process, when a State agency disability examiner makes

the initial determination alone (see § 404.1615(c)(3)), opinions provided by State agency medical and psychological consultants and other program physicians, psychologists, or other medical specialists based on their review of the evidence in your case record (see § 404.1527(e)(1)(ii));

(vii) At the reconsideration level of the administrative review process, when a State agency disability examiner makes the determination alone (see § 404.1615(c)(3)), findings, other than the ultimate determination about whether or not you are disabled, made by the State agency medical or psychological consultants and other program physicians, psychologists, or other medical specialists at the initial level of the administrative review process, and other opinions they provide based on their review of the evidence in your case record at the initial and reconsideration levels (see § 404.1527(e)(1)(iii)); and

(viii) At the administrative law judge and Appeals Council levels, findings, other than the ultimate determination about whether or not you are disabled, made by State agency medical or psychological consultants and other program physicians or psychologists, or other medical specialists, and opinions expressed by medical experts or psychological experts that we consult based on their review of the evidence in your case record (see §§ 404.1527(e)(2)–(3)).

(2) *Exceptions.* Notwithstanding paragraph (b)(1) of this section, evidence does not include:

(i) Oral or written communications between you and your representative that are subject to the attorney-client privilege, unless you voluntarily disclose the communication to us; or

(ii) Your representative’s analysis of your claim, unless he or she voluntarily discloses it to us. Your representative’s “analysis of your claim,” means information that is subject to the attorney work product doctrine, but it does not include medical evidence, medical source opinions, or any other factual matter that we may consider in determining whether or not you are entitled to benefits (see paragraph (b)(2)(iv) of this section).

(iii) The provisions of paragraph (b)(2)(i) apply to communications between you and your non-attorney representative only if the communications would be subject to the attorney-client privilege, if your non-attorney representative were an attorney. The provisions of paragraph (b)(2)(ii) apply to the analysis of your claim by your non-attorney representative only if the analysis of

your claim would be subject to the attorney work product doctrine, if your non-attorney representative were an attorney.

(iv) The attorney-client privilege generally protects confidential communications between an attorney and his or her client that are related to providing or obtaining legal advice. The attorney work product doctrine generally protects an attorney’s analysis, theories, mental impressions, and notes. In the context of your disability claim, neither the attorney-client privilege nor the attorney work product doctrine allows you to withhold factual information, medical source opinions, or other medical evidence that we may consider in determining whether or not you are entitled to benefits. For example, if you tell your representative about the medical sources you have seen, your representative cannot refuse to disclose the identity of those medical sources to us based on the attorney-client privilege. As another example, if your representative asks a medical source to complete an opinion form related to your impairment(s), symptoms, or limitations, your representative cannot withhold the completed opinion form from us based on the attorney work product doctrine. The attorney work product doctrine would not protect the source’s opinions on the completed form, regardless of whether or not your representative used the form in his or her analysis of your claim or made handwritten notes on the face of the report.

(c) *Your responsibility.* You must inform us about or submit all evidence known to you that relates to whether or not you are blind or disabled. When you submit evidence from another source, you must submit that evidence in its entirety. If we ask you, you must inform us about:

- (1) Your medical source(s);
- (2) Your age;
- (3) Your education and training;
- (4) Your work experience;
- (5) Your daily activities both before and after the date you say that you became disabled;
- (6) Your efforts to work; and
- (7) Any other factors showing how your impairment(s) affects your ability to work. In §§ 404.1560 through 404.1569a, we discuss in more detail the evidence we need when we consider vocational factors.

\* \* \* \* \*

**Subpart R—[Amended]**

■ 6. The authority citation for subpart R of part 404 continues to read as follows:

**Authority:** Secs. 205(a), 206, 702(a)(5), and 1127 of the Social Security Act (42 U.S.C. 405(a), 406, 902(a)(5), and 1320a–6).

■ 7. In § 404.1740, revise paragraphs (b)(1) and (b)(2)(i) through (vii) to read as follows:

**§ 404.1740 Rules of conduct and standards of responsibility for representatives.**

\* \* \* \* \*

(b) \* \* \*

(1) Act with reasonable promptness to help obtain the information or evidence that the claimant must submit under our regulations, and forward the information or evidence to us for consideration as soon as practicable.

(2) \* \* \*

- (i) The claimant’s medical source(s);
- (ii) The claimant’s age;
- (iii) The claimant’s education and training;
- (iv) The claimant’s work experience;
- (v) The claimant’s daily activities both before and after the date the claimant alleges that he or she became disabled;
- (vi) The claimant’s efforts to work; and

(vii) Any other factors showing how the claimant’s impairment(s) affects his or her ability to work. In §§ 404.1560 through 404.1569a, we discuss in more detail the evidence we need when we consider vocational factors;

\* \* \* \* \*

**PART 405—ADMINISTRATIVE REVIEW PROCESS FOR ADJUDICATING INITIAL DISABILITY CLAIMS**

■ 8. The authority citation for part 405 continues to read as follows:

**Authority:** Secs. 201(j), 205(a)–(b), (d)–(h), and (s), 221, 223(a)–(b), 702(a)(5), 1601, 1602, 1631, and 1633 of the Social Security Act (42 U.S.C. 401(j), 405(a)–(b), (d)–(h), and (s), 421, 423(a)–(b), 902(a)(5), 1381, 1381a, 1383, and 1383b).

■ 9. In § 405.1, revise the first sentence of paragraph (c)(2) to read as follows:

**Subpart A—[Amended]**

**§ 405.1 Introduction.**

\* \* \* \* \*

(c) \* \* \*

(2) *Evidence considered and right to representation.* Subject to §§ 405.331 and 405.430, you must submit evidence and information to us (see §§ 404.1512 and 416.912). \* \* \*

\* \* \* \* \*

■ 10. In § 405.331, revise the first two sentences of paragraph (a) to read as follows:

**Subpart D—[Amended]****§ 405.331 Submitting evidence to an administrative law judge.**

(a) When you submit your request for hearing, you should also submit information or evidence as required by §§ 404.1512 or 416.912 of this chapter or any summary of the evidence to the administrative law judge. You must submit any written evidence no later than 5 business days before the date of the scheduled hearing. \* \* \*

\* \* \* \* \*

**PART 416—SUPPLEMENTAL SECURITY INCOME FOR THE AGED, BLIND, AND DISABLED****Subpart I—[Amended]**

■ 11. The authority citation for subpart I of part 416 continues to read as follows:

**Authority:** Secs. 221(m), 702(a)(5), 1611, 1614, 1619, 1631(a), (c), (d)(1), and (p), and 1633 of the Social Security Act (42 U.S.C. 421(m), 902(a)(5), 1382, 1382c, 1382h, 1383(a), (c), (d)(1), and (p), and 1383b); secs. 4(c) and 5, 6(c)–(e), 14(a), and 15, Pub. L. 98–460, 98 Stat. 1794, 1801, 1802, and 1808 (42 U.S.C. 421 note, 423 note, and 1382h note).

■ 12. In § 416.912, revise paragraphs (a) through (c) to read as follows:

**§ 416.912 Evidence.**

(a) *General.* In general, you have to prove to us that you are blind or disabled. You must inform us about or submit all evidence known to you that relates to whether or not you are blind or disabled. We will consider only impairment(s) you say you have or about which we receive evidence.

(b) *What we mean by “evidence.”* Evidence is anything you or anyone else submits to us or that we obtain that relates to your claim.

(1) Evidence includes, but is not limited to:

(i) Objective medical evidence, that is, medical signs and laboratory findings as defined in § 416.928(b) and (c);

(ii) Other evidence from medical sources, such as medical history, opinions, and statements about treatment you have received;

(iii) Statements you or others make about your impairment(s), your restrictions, your daily activities, your efforts to work, or any other statements you make to medical sources during the course of examination or treatment, or to us during interviews, on applications, in letters, and in testimony in our administrative proceedings;

(iv) Information from other sources, as described in § 416.913(d);

(v) Decisions by any governmental or nongovernmental agency about whether

or not you are disabled or blind (*see* § 404.1504);

(vi) At the initial level of the administrative review process, when a State agency disability examiner makes the initial determination alone (*see* § 416.1015(c)(3)), opinions provided by State agency medical and psychological consultants and other program physicians, psychologists, or other medical specialists based on their review of the evidence in your case record (*see* § 416.927(e)(1)(ii));

(vii) At the reconsideration level of the administrative review process, when a State agency disability examiner makes the determination alone (*see* § 416.1015(c)(3)), findings, other than the ultimate determination about whether or not you are disabled, made by the State agency medical or psychological consultants and other program physicians, psychologists, or other medical specialists at the initial level of the administrative review process, and other opinions they provide based on their review of the evidence in your case record at the initial and reconsideration levels (*see* § 416.927(e)(1)(iii)); and

(viii) At the administrative law judge and Appeals Council levels, findings, other than the ultimate determination about whether or not you are disabled, made by State agency medical or psychological consultants and other program physicians or psychologists, or other medical specialists, and opinions expressed by medical experts or psychological experts that we consult based on their review of the evidence in your case record (*see* §§ 416.927(e)(2)–(3)).

(2) *Exceptions.* Notwithstanding paragraph (b)(1) of this section, evidence does not include:

(i) Oral or written communications between you and your representative that are subject to the attorney-client privilege, unless you voluntarily disclose the communication to us; or

(ii) Your representative’s analysis of your claim, unless he or she voluntarily discloses it to us. Your representative’s “analysis of your claim,” means information that is subject to the attorney work product doctrine, but it does not include medical evidence, medical source opinions, or any other factual matter that we may consider in determining whether or not you are eligible for benefits (*see* paragraph (b)(2)(iv) of this section).

(iii) The provisions of paragraph (b)(2)(i) apply to communications between you and your non-attorney representative only if the communications would be subject to the attorney-client privilege, if your non-

attorney representative were an attorney. The provisions of paragraph (b)(2)(ii) apply to the analysis of your claim by your non-attorney representative only if the analysis of your claim would be subject to the attorney work product doctrine, if your non-attorney representative were an attorney.

(iv) The attorney-client privilege generally protects confidential communications between an attorney and his or her client that are related to providing or obtaining legal advice. The attorney work product doctrine generally protects an attorney’s analysis, theories, mental impressions, and notes. In the context of your disability claim, neither the attorney-client privilege nor the attorney work product doctrine allows you to withhold factual information, medical source opinions, or other medical evidence that we may consider in determining whether or not you are eligible for benefits. For example, if you tell your representative about the medical sources you have seen, your representative cannot refuse to disclose the identity of those medical sources to us based on the attorney-client privilege. As another example, if your representative asks a medical source to complete an opinion form related to your impairment(s), symptoms, or limitations, your representative cannot withhold the completed opinion form from us based on the attorney work product doctrine. The attorney work product doctrine would not protect the source’s opinions on the completed form, regardless of whether or not your representative used the form in his or her analysis of your claim or made handwritten notes on the face of the report.

(c) *Your responsibility.* You must inform us about or submit all evidence known to you that relates to whether or not you are blind or disabled. When you submit evidence from another source, you must submit that evidence in its entirety. If we ask you, you must inform us about:

- (1) Your medical source(s);
- (2) Your age;
- (3) Your education and training;
- (4) Your work experience;
- (5) Your daily activities both before and after the date you say that you became disabled;
- (6) Your efforts to work; and
- (7) Any other factors showing how your impairment(s) affects your ability to work. In §§ 416.960 through 416.969a, we discuss in more detail the evidence we need when we consider vocational factors.

\* \* \* \* \*

**Subpart N—[Amended]**

■ 13. The authority citation for subpart N of part 416 continues to read as follows:

**Authority:** Secs. 702(a)(5), 1631, and 1633 of the Social Security Act (42 U.S.C. 902(a)(5), 1383, and 1383b); sec. 202, Pub. L. 108–203, 118 Stat. 509 (42 U.S.C. 902 note).

■ 14. Amend § 416.1400 by revising paragraph (b) to read as follows:

**§ 416.1400 Introduction**

\* \* \* \* \*

(b) *Nature of the administrative review process.* In making a determination or decision in your case, we conduct the administrative review process in an informal, non-adversarial manner. Subject to the limitations on Appeals Council consideration of additional evidence (*see* §§ 416.1470(b) and 416.1476(b)), we will consider at each step of the review process any information you present as well as all the information in our records. You may present the information yourself or have someone represent you, including an attorney. If you are dissatisfied with our decision in the review process, but do not take the next step within the stated time period, you will lose your right to further administrative review and your right to judicial review, unless you can show us that there was good cause for your failure to make a timely request for review.

\* \* \* \* \*

■ 15. Revise § 416.1435 to read as follows:

**§ 416.1435 Submitting evidence prior to a hearing before an administrative law judge.**

You should submit information or evidence as required by § 416.912 or any summary of the evidence to the administrative law judge with the request for hearing or within 10 days after filing the request, if possible. Each party shall make every effort to ensure that the administrative law judge receives all of the evidence (*see* § 416.912) or all of the evidence is available at the time and place set for the hearing.

**Subpart O—[Amended]**

■ 16. The authority citation for subpart O of part 416 continues to read as follows:

**Authority:** Secs. 702(a)(5), 1127, and 1631(d) of the Social Security Act (42 U.S.C. 902(a)(5), 1320a–6, and 1383(d)).

■ 17. In § 416.1540, revise paragraphs (b)(1) and (b)(2)(i) through (vii) to read as follows:

**§ 416.1540 Rules of conduct and standards of responsibility for representatives.**

\* \* \* \* \*

(b) \* \* \*

(1) Act with reasonable promptness to help obtain the information or evidence that the claimant must submit under our regulations, and forward the information or evidence to us for consideration as soon as practicable.

(2) \* \* \*

(i) The claimant's medical source(s);

(ii) The claimant's age;

(iii) The claimant's education and training;

(iv) The claimant's work experience;

(v) The claimant's daily activities both before and after the date the claimant alleges that he or she became disabled;

(vi) The claimant's efforts to work; and

(vii) Any other factors showing how the claimant's impairment(s) affects his or her ability to work. In §§ 416.960 through 416.969a, we discuss in more detail the evidence we need when we consider vocational factors;

\* \* \* \* \*

[FR Doc. 2014–03426 Filed 2–19–14; 8:45 am]

BILLING CODE 4191–02–P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration****21 CFR Part 890**

[Docket No. FDA–2012–N–0378]

**Physical Medicine Devices; Withdrawal of Proposed Effective Date of Requirement for Premarket Approval for Shortwave Diathermy for All Other Uses****AGENCY:** Food and Drug Administration, HHS.**ACTION:** Proposed rule; withdrawal.

**SUMMARY:** The Food and Drug Administration (FDA) is withdrawing the proposed rule the Agency issued in the *Federal Register* of July 6, 2012. In that document, FDA proposed to require the filing of a premarket approval application (PMA) or a notice of completion of a product development protocol (PDP) for the class III preamendment device, shortwave diathermy (SWD) for all other uses. In response to the requirements issued in the Food and Drug Administration Safety and Innovation Act (FDASIA) and new information received during a panel meeting, FDA is withdrawing the proposed rule and proposing a different action.

**DATES:** The proposed rule is withdrawn on February 20, 2014.

**FOR FURTHER INFORMATION CONTACT:**

Melissa Burns, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1646, Silver Spring, MD 20993, 301–796–5616, *Melissa.Burns@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:****I. Background—Regulatory Authorities**

In the *Federal Register* of July 6, 2012 (77 FR 39953), FDA issued a proposed rule to require the filing of a PMA or a notice of completion of a PDP for the class III preamendments device, SWD for all other uses. This device applies electromagnetic energy to the body in the radio frequency bands that are currently identified as 13.56 megahertz or 27.12 megahertz and is intended for the treatment of medical conditions by means other than the generation of deep heat within body tissues (also referred to as nonthermal SWD). It is not intended for treatment of malignancies. The Agency also summarized its proposed findings regarding the degree of risk of illness or injury designed to be eliminated or reduced by requiring the devices to meet the statute's approval requirements and the benefits to the public from the use of the devices. In addition, FDA announced the opportunity for interested persons to request that the Agency change the classification of any of the aforementioned devices based on new information.

On July 9, 2012, FDASIA was enacted. Section 608(a) of FDASIA (126 Stat. 1056) amended section 513(e) (U.S.C. 360c(e)) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) changing the process for reclassifying a device from rulemaking to an administrative order. Subsequent to the publication of the proposed rule, FDASIA's amendments to section 513 of the FD&C Act required FDA to hold a classification panel (an FDA advisory committee) meeting on the classification of this device. On May 21, 2013, FDA held a meeting of the Orthopedic and Rehabilitation Devices Panel (the Panel), to discuss the classification of nonthermal SWD devices. There was panel consensus that although the effectiveness data were very limited, nonthermal SWD devices did not fit the regulatory definition of a class III device. Coupled with the rationale that special controls could be established to reasonably demonstrate an assurance of safety and effectiveness, the Panel recommended class II (special controls) for nonthermal SWD devices (Ref. 1).