## 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 $\S 39.13$ by adding the following new AD :
DG Flugzeugbau GmbH: Docket No. FAA-2008-0649; Directorate Identifier 2008-CE-038-AD.

## Comments Due Date

(a) We must receive comments by July 14, 2008.

## Affected ADs

(b) None.

## Applicability

(c) This AD applies to DG-500MB powered sailplanes, all serial numbers, certificated in any category.

## Subject

(d) Air Transport Association of America (ATA) Code 71: Power Plant.

## Reason

(e) The mandatory continuing airworthiness information (MCAI) states: A DG-500MB experienced, after the engine shutdown, an uncommanded retraction of its powerplant.
Investigations revealed that some bolts of the extension retraction mechanism had fractured because of fatigue stress due to increasing push-pull loads acting on incorrectly tightened screws.
This condition, if not corrected, could lead to damage of the propeller and the fuselage, thereby reducing the structural integrity of the sailplane.
To address this unsafe condition, this Airworthiness Directive mandates the replacement of eight bolts, the four connecting the fork 5M203 to the 5M204 adapter and those connecting the adapter 5M204 to the spindle drive, by new ones of higher strength and, a rework of the coupling of the 5M203 fork to the 5M204 adapter as well as the coupling of the 5M204 adapter to the spindle drive, by glueing the parts together, in addition to the pre-existing bolts.

## Actions and Compliance

(f) Unless already done, within the next 30 days after the effective date of this AD, modify the spindle drive assembly in accordance with DG Flugzeugbau GmbH Technical Note No. 843/27, dated April 14, 2008.

## FAA AD Differences

Note: This AD differs from the MCAI and/ or service information as follows: No differences.

## Other FAA AD Provisions

(g) 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: Greg Davison, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329-4130; fax: (816) 3294090. Before using any approved AMOC on any powered sailplane 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 , under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 et seq.), the Office of Management and Budget (OMB) has approved the information collection requirements and has assigned OMB Control Number 2120-0056.

## Related Information

(h) Refer to MCAI European Aviation Safety Agency (EASA) AD No. 2008-0095, dated May 16, 2008; and DG Flugzeugbau GmbH Technical Note No. 843/27, dated April 14, 2008, for related information.

Issued in Kansas City, Missouri, on June 6, 2008.

## David R. Showers,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.
[FR Doc. E8-13324 Filed 6-12-08; 8:45 am] BILLING CODE 4910-13-P

## SOCIAL SECURITY ADMINISTRATION

## 20 CFR Parts 404, 408, 416, and 422

[Docket No. SSA-2008-0005]
RIN 0960-AG75

## Clarification of Evidentiary Standard for Determinations and Decisions

AGENCY: Social Security Administration. ACTION: Notice of Proposed Rulemaking.

SUMMARY: These proposed rules clarify that we apply the preponderance of the evidence standard when we make determinations and decisions at all levels of our administrative review processes. These proposed rules would not change our policy that the Appeals Council applies the substantial evidence standard when it reviews an administrative law judge's decision to determine whether to grant a request for review. We also propose to explicitly define substantial evidence and
preponderance of the evidence in applying these rules.
DATES: To be sure that your comments are considered, we must receive them no later than August 12, 2008.
ADDRESSES: You may submit comments by any one of four methods-Internet, facsimile, regular mail, or handdelivery. Commenters should not submit the same comments multiple times or by more than one method. Regardless of which of the following methods you choose, please state that your comments refer to Docket No. SSA-2008-0005 to ensure that we can associate your comments with the correct regulation:

1. Federal eRulemaking portal at http://www.regulations.gov. (This is the most expedient method for submitting your comments, and we strongly urge you to use it.) In the "Comment or Submission" section of the Web page, type "SSA-2008-0005", select "Go," and then click "Send a Comment or Submission." The Federal eRulemaking portal issues you a tracking number when you submit a comment.
2. Telefax to (410) 966-2830.
3. Letter to the Commissioner of Social Security, P.O. Box 17703, Baltimore, MD 21235-7703.
4. Deliver your comments to the Office of Regulations, Social Security Administration, 922 Altmeyer Building, 6401 Security Boulevard, Baltimore, Maryland 21235-6401, between 8 a.m. and 4:30 p.m. on regular business days.

All comments are posted on the Federal eRulemaking portal, although they may not appear for several days after receipt of the comment. You may also inspect the comments on regular business days by making arrangements with the contact person shown in this preamble.
Caution: All comments we receive from members of the public are available for public viewing on the Federal eRulemaking portal at http:// www.regulations.gov. Therefore, you should be careful to include in your comments only information that you wish to make publicly available on the Internet. We strongly urge you not to include any personal information, such as your Social Security number or medical information, in your comments.
FOR FURTHER INFORMATION CONTACT:
Joshua Silverman, Office of Regulations, Social Security Administration, 6401 Security Boulevard, Baltimore, MD 21235-6401, (410) 594-2128, for information about these rules. 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:

## Electronic Version

The electronic file of this document is available on the date of publication in the Federal Register at http:// www.gpoaccess.gov/fr/index.html.

## Explanation of Changes

## Our Administrative Review Process

We currently decide claims for benefits using an administrative review process that consists of four levels. See 20 CFR 404.900, 408.1000, and 416.1400. We make our initial determination at the first level. In most States, ${ }^{1}$ if an individual is dissatisfied with our initial determination, the individual may request reconsideration. If an individual is dissatisfied with the reconsidered determination, the individual may request a hearing before an administrative law judge (ALJ). ${ }^{2}$ Finally, if an individual is dissatisfied with the ALJ's decision, ${ }^{3}$ the individual may request that the Appeals Council review the ALJ's decision. Once an individual has completed these administrative steps and received our final decision, the individual may request judicial review of the final decision in Federal district court.

At the initial, reconsideration, and ALJ levels of the administrative review process, adjudicators make a new decision based on the evidence in the case record. ${ }^{4}$ For example, ALJs do not

[^0]review the State agency's initial and reconsideration determinations to determine whether they were supported or correctly made; rather, they make their own new decisions.

However, when an individual is dissatisfied with an ALJ's decision and asks the Appeals Council to "review" that decision, the Appeals Council first considers the ALJ's decision and the evidence before the ALJ to determine whether to grant the request for review. If the Appeals Council does not grant the request for review, the ALJ's decision becomes our final decision. ${ }^{5}$ However, if the Appeals Council grants the request for review, it will generally either remand the case to an ALJ for additional proceedings and a new decision or issue its own decision affirming, modifying, or reversing the ALJ's decision.

## Our Standard of Evidence

Adjudicators at each level of the administrative review process use an evidentiary standard called the "preponderance of the evidence" when they make a determination or decision. As we state in proposed $\S \S 404.901$ and 416.1401 below, we define this standard as meaning "such relevant evidence that as a whole shows that the existence of the fact to be proven is more likely than not."

However, when the Appeals Council considers an ALJ's decision and whether to grant a request for review, it does not use a preponderance of the evidence standard. Instead, it considers four issues, including whether the action, findings, or conclusions of the ALJ are supported by substantial evidence. $\S \S 404.970$ and 416.1470. The substantial evidence standard is different from the preponderance of the evidence standard and is more deferential to the findings of the ALJ.

While our policy has been that the preponderance of the evidence standard applies when we make determinations or decisions on claims under parts 404, 408 , and 416, we do not have any regulations that say this clearly. The absence of explicit language in parts 404, 408, and 416 explaining the standards we use at each level of the administrative process has caused some

[^1]confusion about the applicable standard. ${ }^{6}$

## Proposed Changes

We propose to revise several regulation sections in parts 404, 408, 416 , and 422 to explicitly state that we use the preponderance of the evidence standard to adjudicate claims at all levels of the administrative review process. We also propose to add definitions of the terms "preponderance of the evidence" and "substantial evidence" in $\S \S 404.901,408.1001$, and 416.1401.

The proposed definitions of "preponderance of the evidence" and "substantial evidence" are the same definitions we currently use in §405.5. We believe these clarifications will improve the accuracy and consistency of the decision-making process.
Sections 205(a), 702(a)(5), 810(a), and 1631(d)(1) of the Act authorize the Commissioner of Social Security to prescribe these rule changes.

## Clarity of These Proposed Rules

Executive Order (E.O.) 12866, as amended, requires each agency to write all rules in plain language. In addition to your substantive comments on these final rules, we invite your comments on how to make them easier to understand.

For example:

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


## Regulatory Procedures

## Executive Order 12866, as Amended

We have consulted with the Office of Management and Budget (OMB) and determined that these proposed rules do not meet the criteria for a significant regulatory action under Executive Order 12866 , as amended. Thus, they were not subject to OMB review.

## Regulatory Flexibility Act

We certify that these proposed rules will not have a significant economic

[^2]impact on a substantial number of small entities as they affect individuals only. Therefore, a regulatory flexibility analysis as provided in the Regulatory Flexibility Act, as amended, is not required.

## Paperwork Reduction Act

These rules would impose no additional reporting or recordkeeping requirements requiring OMB clearance.
(Catalog of Federal Domestic Assistance Program Nos. 96.001, Social SecurityDisability Insurance; 96.002, Social Security-Retirement Insurance; 96.004, Social Security-Survivors Insurance; 96.006, Supplemental Security Income)

## 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 408

Administrative practice and procedure; Aged; Reporting and recordkeeping requirements; Social Security; Supplemental Security Income (SSI); Veterans.

## 20 CFR Part 416

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

## 20 CFR Part 422

Administrative practice and procedure; Organization and functions (Government agencies); Reporting and recordkeeping requirements; Social Security.
Dated: June 6, 2008.
Michael J. Astrue,
Commissioner of Social Security.
For the reasons set forth in the preamble, we propose to amend subpart J of part 404, subpart J of part 408, subpart N of part 416, and subparts B and C of part 422 of chapter III of title 20 of the Code of Federal Regulations 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 $\S 404.901$ by adding the definitions for "Preponderance of the evidence" and "Substantial evidence" in alphabetical order to read as follows:

## §404.901 Definitions.

Preponderance of the evidence means such relevant evidence that as a whole shows that the existence of the fact to be proven is more likely than not.

Substantial evidence means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.
3. Amend $\S 404.902$ by revising the second sentence in the undesignated first paragraph to read as follows:

## § 404.902 Administrative actions that are

 initial determinations.*     *         * The initial determination will state the important facts, give the reasons for our conclusions, and be based on the preponderance of the evidence. * * *

4. Amend § 404.917 by revising the second sentence of paragraph (b) to read as follows:

## §404.917 Disability hearing-disability hearing officer's reconsidered determination.

(b) * * * The reconsidered determination must be based on the preponderance of the evidence offered at the disability hearing or otherwise included in your case file.
5. Revise § 404.920 to read as follows:

## §404.920 Reconsidered determination.

After you or another person requests a reconsideration, we will review the evidence considered in making the initial determination and any other evidence we receive. We will make our determination based on the preponderance of the evidence.
6. Amend $\S 404.941$ by revising the second sentence of paragraph (a) to read as follows:
§404.941 Prehearing case review.
(a) * * * That component will decide whether the determination may be revised based on the preponderance of the evidence. * * *

*     *         *             *                 * 

7. Amend $\S 404.942$ by revising the second sentence of paragraph (a) to read as follows:

## §404.942 Prehearing proceedings and decisions by attorney advisors.

(a) * * * If upon the completion of these proceedings, a decision that is wholly favorable to you and all other parties may be made based on the preponderance of the evidence, an attorney advisor, instead of an administrative law judge, may issue such a decision. * * *
8. Amend $\S 404.948$ by revising the first sentence of paragraph (a) to read as follows:
§404.948 Deciding a case without an oral hearing before an administrative law judge.
(a) * * * If the evidence in the hearing record supports a finding in favor of you and all the parties on every issue, the administrative law judge may issue a hearing decision based on a preponderance of the evidence without holding an oral hearing. * * *
9. Amend $\S 404.953$ by revising the second sentence of paragraph (a), the first sentence in paragraph (b), and the first sentence of paragraph (c) to read as follows:

## §404.953 The decision of an administrative law judge.

(a) * * * The decision must be based on the preponderance of the evidence offered at the hearing or otherwise included in the record.
(b) * * * The administrative law judge may enter a wholly favorable oral decision based on the preponderance of the evidence into the record of the hearing proceedings. * * *
(c) * * * Although an administrative law judge will usually make a decision, where appropriate, he or she may send the case to the Appeals Council with a recommended decision based on a preponderance of the evidence. * * *
10. Amend $\S 404.979$ by adding a new third sentence to read as follows:

## §404.979 Decision of Appeals Council.

*     *         * If the Appeals Council issues its own decision, the decision will be based upon the preponderance of the evidence. * * *

11. Amend $\S 404.984$ by revising the last sentence in paragraph (a), the second sentence of paragraph (b)(3), and the last sentence in paragraph (c) to read as follows:
§404.984 Appeals Council review of administrative law judge decision in a case remanded by a Federal court.
(a) * * * The Appeals Council will either make a new, independent decision based on the preponderance of the evidence in the record that will be the final decision of the Commissioner after remand, or remand the case to an administrative law judge for further proceedings.
(b) * * *
(3) * * * If the Appeals Council assumes jurisdiction, it will make a new, independent decision based on the preponderance of the evidence in the entire record affirming, modifying, or reversing the decision of the administrative law judge, or remand the case to an administrative law judge for further proceedings, including a new decision. * * *
(c) * * * After the briefs or other written statements have been received or the time allowed (usually 30 days) for submitting them has expired, the Appeals Council will either issue a final decision of the Commissioner based on the preponderance of the evidence affirming, modifying, or reversing the decision of the administrative law judge, or remand the case to an administrative law judge for further proceedings, including a new decision.

## PART 408-SPECIAL BENEFITS FOR CERTAIN WORLD WAR II VETERANS

## Subpart J—[Amended]

12. The authority citation for subpart J of part 408 continues to read as follows:
Authority: Secs. 702(a)(5) and 809 of the Social Security Act (42 U.S.C. 902(a)(5) and 1009).
13. Amend $\S 408.1001$ by adding the definition " Preponderance of the evidence" in alphabetical order to read as follows:

## §408.1001 Definitions.

Preponderance of the evidence means such relevant evidence that as a whole shows that the existence of the fact to be proven is more likely than not.
14. Amend $\S 408.1002$ by adding a new third sentence to read as follows:

## § 408.1002 What is an initial determination?

*     *         * Initial determinations are based on the preponderance of the evidence.

15. Amend the second sentence in $\S 408.1020$ by revising it to read as follows:

## §408.1020 How do we make our

 reconsidered determination?*     *         * We will make our
determination based on the preponderance of the evidence in the record. * * *


## PART 416-SUPPLEMENTAL SECURITY INCOME FOR THE AGED, BLIND, AND DISABLED

## Subpart N-[Amended]

16. 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).
17. Amend $\S 416.1401$ by adding the definitions for "Preponderance of the evidence" and "Substantial evidence" in alphabetical order to read as follows:

## §416.1401 Definitions.

Preponderance of the evidence means such relevant evidence that as a whole shows that the existence of the fact to be proven is more likely than not.

Substantial evidence means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.
18. Amend $\S 416.1402$ by revising the second sentence in the undesignated first paragraph to read as follows:
§416.1402 Administrative actions that are initial determinations.

*     *         * The initial determination will state the important facts, give the reasons for our conclusions, and be based on the preponderance of the evidence. * * *

19. Amend $\S 416.1417$ by revising the second sentence of paragraph (b) to read as follows:

## §416.1417 Disability hearing-disability hearing officer's reconsidered determination. <br> (b) * * * The reconsidered

determination must be based on the preponderance of the evidence offered at the disability hearing or otherwise included in your case file.
20. Revise $\S 416.1420$ to read as follows:

## §416.1420 Reconsidered determination.

After you or another person requests a reconsideration, we will review the
evidence considered in making the initial determination and any other evidence we receive. We will make our determination based on the preponderance of the evidence. The person who makes the reconsidered determination will have had no prior involvement with the initial determination.
21. Amend $\S 416.1441$ by revising the second sentence of paragraph (a) to read as follows:

## §416.1441 Prehearing case review.

(a) * * * That component will decide whether the determination may be revised based on the preponderance of the evidence. * * *
22. Amend $\S 416.1442$ by revising the second sentence of paragraph (a) to read as follows:
§416.1442 Prehearing proceedings and decisions by attorney advisors.
(a) * * * If upon the completion of these proceedings, a decision that is wholly favorable to you and all other parties may be made based on the preponderance of the evidence, an attorney advisor, instead of an administrative law judge, may issue such a decision. * * *
23. Amend § 416.1448 by revising the first sentence of paragraph (a) to read as follows:
§416.1448 Deciding a case without an oral hearing before an administrative law judge.
(a) * * * If the evidence in the hearing record supports a finding in favor of you and all the parties on every issue, the administrative law judge may issue a hearing decision based on a preponderance of the evidence without holding an oral hearing. * * *
24. Amend $\S 416.1453$ by revising the second sentence of paragraph (a), the first sentence of paragraph (b), and the first sentence of paragraph (d) to read as follows:

## §416.1453 The decision of an administrative law judge.

(a) * * * The decision must be based on the preponderance of the evidence offered at the hearing or otherwise included in the record.
(b) * * * The administrative law judge may enter a wholly favorable oral decision based on the preponderance of the evidence into the record of the hearing proceedings. * * *
(d) * * *Although an administrative law judge will usually make a decision, where appropriate, he or she may send
the case to the Appeals Council with a recommended decision based on a preponderance of the evidence. * * *
25 . Amend $\S 416.1479$ by adding a new third sentence to read as follows:

## §416.1479 Decision of Appeals Council.

*     *         * If the Appeals Council issues its own decision, the decision will be based upon the preponderance of the evidence. * * *

26. Amend $\S 416.1484$ by revising the last sentence in paragraph (a), the second sentence of paragraph (b)(3), and the last sentence in paragraph (c) to read as follows:
§416.1484 Appeals Council review of administrative law judge decision in a case remanded by a Federal court.
(a) * * * The Appeals Council will either make a new, independent decision based on the preponderance of the evidence in the record that will be the final decision of the Commissioner after remand, or remand the case to an administrative law judge for further proceedings.
(b) * * *
(3) * * * If the Appeals Council assumes jurisdiction, it will make a new, independent decision based on the preponderance of the evidence in the entire record affirming, modifying, or reversing the decision of the administrative law judge, or remand the case to an administrative law judge for further proceedings, including a new decision. * * *
(c) * * * After the briefs or other written statements have been received or the time allowed (usually 30 days) for submitting them has expired, the Appeals Council will either issue a final decision of the Commissioner based on the preponderance of the evidence affirming, modifying, or reversing the decision of the administrative law judge, or remand the case to an administrative law judge for further proceedings, including a new decision.

## PART 422-ORGANIZATION AND PROCEDURES

## Subpart B-[Amended]

27. The authority citation for subpart B of part 422 continues to read as follows:
Authority: Secs. 205, 232, 702(a)(5), 1131, and 1143 of the Social Security Act ( 42 U.S.C. 405, 432, 902(a)(5), 1320b-1, and 1320b-13), and sec. 7213(a)(1)(A) of Pub. L. 108-458.
28. Amend § 422.130 by revising the first sentence of paragraph (c) to read as follows:

## §422.130 Claim procedure.

*     *         *             *                 * 

(c) * * * In the case of an application for benefits, the establishment of a period of disability, a lump-sum death payment, a recomputation of a primary insurance amount, or entitlement to hospital insurance benefits or supplementary medical insurance benefits, the Social Security Administration, after obtaining the necessary evidence, will make a determination based on the preponderance of the evidence (see $\S \S 404.901$ and 416.1401 ) as to the entitlement of the individual claiming or for whom is claimed such benefits, and will notify the applicant of the determination and of his right to appeal.

## Subpart C-[Amended]

29. The authority citation for subpart C of part 422 continues to read as follows:
Authority: Secs. 205, 221, and 702(a)(5) of the Social Security Act (42 U.S.C. 405, 421, and 902(a)(5)); 30 U.S.C. 923(b).
30. Revise the last sentence of §422.203(c) to read as follows:

## §422.203 Hearings.

(c) * * * Hearing decisions must be based on the preponderance of the evidence of record, under applicable provisions of the law and regulations and appropriate precedents.
[FR Doc. E8-13282 Filed 6-12-08; 8:45 am] BILLING CODE 4191-02-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

## 21 CFR Part 803

[Docket No. FDA-2008-N-0310]
Medical Devices; Medical Device
Reporting; Baseline Reports; Companion to Direct Final Rule
AgENCY: Food and Drug Administration, HHS.
ACTION: Proposed rule.
summary: The Food and Drug Administration (FDA) is proposing to amend its medical device reporting regulations to remove a requirement for baseline reports that the agency deems no longer necessary. Currently, manufacturers provide baseline reports to FDA that include the FDA product code and the premarket approval or
premarket notification number. Because most of the information in these baseline reports is also submitted to FDA in individual adverse event reports, FDA is proposing to remove the requirement for baseline reports. The removal of this requirement would eliminate unnecessary duplication and reduce the manufacturer's reporting burden. This proposed rule is a companion document to the direct final rule published elsewhere in this issue of the Federal Register.
DATES: Submit written or electronic comments by August 27, 2008.
ADDRESSES: You may submit comments, identified by Docket No. FDA-2008-N0310, by any of the following methods:

## Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http:// www.regulations.gov. Follow the instructions for submitting comments. Written Submissions

Submit written submissions in the following ways:

- FAX: 301-827-6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]: Division of Dockets Management (HFA305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by email. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal, as described previously, in the ADDRESSES portion of this document under

## Electronic Submissions.

Instructions: All submissions received must include the agency name and Docket No. for this rulemaking. All comments received may be posted without change to http:// www.regulations.gov, including any personal information provided. For additional information on submitting comments, see section IX of this document.

Docket: For access to the docket to read background documents or comments received, go to http:// www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search"' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
FOR FURTHER INFORMATION CONTACT:
Howard A. Press, Center for Devices and Radiological Health (HFZ-530), Food and Drug Administration, 1350 Piccard Dr, Rockville, MD 20850, 240-2763457.


[^0]:    ${ }^{1}$ For claims for disability benefits, there are ten States that are participating in a "prototype" test under $\S \S 404.906$ and 416.1406. In these States, the second step for individuals who are dissatisfied with their initial determinations in disability cases is a hearing before an ALJ. The ten States are: Alabama, Alaska, California (Los Angeles North and West Branches), Colorado, Louisiana, Michigan, Missouri, New Hampshire, New York, and Pennsylvania.
    ${ }^{2}$ In some cases, attorney advisors in our Office of Disability Adjudication and Review may make wholly favorable decisions before an ALJ hearing is conducted. See $\S \$ 404.942$ and 416.1442 .
    ${ }^{3}$ The words "determination" and "decision" are terms that are defined in $\S \S 404.900$ and 416.1400. At the initial and reconsideration levels of the administrative review process, we issue
    "determinations." At the ALJ hearing and Appeals Council levels (when the Appeals Council makes a decision), we issue "decisions."
    ${ }^{4}$ In some States, adjudicators must consider, and sometimes adopt, certain findings made in prior adjudications under acquiescence rulings (ARs) we have issued to address circuit court holdings. See AR 97-4(9), 62 FR 64308, available at: http:// www.socialsecurity.gov/OP_Home/rulings/ar/09/ AR97-04-ar-09.html; AR 98-3(6), 63 FR 29770, available at: http://www/socialsecurity.gov/ OP_Home/rulings/ar/06/AR98-03-ar-06.html.; AR-98-4(6), 63 FR 29771, corrected at 63 FR 31266, available at: http://www.socialsecurity.gov/OP Home/rulings/ar/06/AR98-04-ar-06.html; and AR 00-1(4), 65 FR 1936, available at: http://

[^1]:    www.socialsecurity.gov/OP__Homing/rulings/ar/04/ AR2000-01-ar-04.html.
    ${ }^{5}$ The Appeals Council may also dismiss the request for review either with or without granting the request first. It may also review a case on its own motion; that is, without an individual asking it to do so. See $\S \S 404.967,404.969,404.984$, 416.1467, 416.1469, and 416.1484. See also §408.1050, which incorporates the relevant provisions of $\S \S 416.1467-416.1482$ by reference.

[^2]:    ${ }^{6}$ Federal courts also consider whether the Agency's findings are supported by substantial evidence or whether there is an error of law. 42 U.S.C. 405 (g), 1009(b), and 1383(c)(3).

