

SOCIAL SECURITY ADMINISTRATION**20 CFR Parts 404 and 416**

[Docket No. SSA-2016-0014]

RIN 0960-AH94

Extension of the Expiration Date for State Disability Examiner Authority To Make Fully Favorable Quick Disability Determinations and Compassionate Allowance Determinations**AGENCY:** Social Security Administration.
ACTION: Final rule.

SUMMARY: We are extending, until December 28, 2018, the expiration date of our disability examiner authority (DEA) rule, which authorizes State agency disability examiners to make fully favorable determinations without the approval of a State agency medical or psychological consultant in claims that we consider under our quick disability determination (QDD) and compassionate allowance (CAL) processes. This is our last extension of this rule because we will phase out the use of DEA during the extension period under section 832 of the Bipartisan Budget Act of 2015 (BBA). This extension provides us the time necessary to take all of the administrative actions we need to take in order to reinstate uniform use of medical and psychological consultants. The current rule will expire on November 11, 2016. In this final rule, we are changing the November 11, 2016 expiration or “sunset” date to December 28, 2018, extending the authority for 2 years and 1 month. This is the final extension of our DEA rule. On December 28, 2018, at the conclusion of this extension, the authority for this test will terminate. We are making no other changes.

DATES: This final rule is effective October 24, 2016.

FOR FURTHER INFORMATION CONTACT: Kenneth Williams, Office of Disability Policy, Social Security Administration, 6401 Security Boulevard, Baltimore, MD 21235-6401, (410) 965-0608, for information about this notice. 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 of the QDD and CAL Disability Examiner Authority**

On October 13, 2010, we published a final rule that temporarily authorized State agency disability examiners to

make fully favorable determinations without the approval of a State agency medical or psychological consultant in claims that we consider under our QDD and CAL processes. 75 FR 62676.

We included in 20 CFR 404.1615(c)(3) and 416.1015(c)(3) a sunset date, under which the DEA would expire on November 12, 2013, unless we decided to terminate it earlier or extend it by publication of a final rule in the **Federal Register**. Since that time, we have extended the DEA rule three times for one year each. 78 FR 66638; 79 FR 51241; 80 FR 63092. The last extension we published continues the DEA until November 11, 2016. 80 FR 63092.

Explanation of Provision

This final rule extends the expiration date of the DEA rule until December 28, 2018. Extending the DEA rule provides us with the time necessary for an orderly phase out of the DEA rule, and will allow us to discontinue the use of the DEA under section 832 of the Bipartisan Budget Act of 2015 (BBA).¹ At the conclusion of this extension, by December 28, 2018, the authority for this test will terminate.

Regulatory Procedures**Justification for Issuing a Final Rule Without Notice and Comment**

We follow the Administrative Procedure Act (APA) rulemaking procedures specified in 5 U.S.C. 553 when developing regulations. Section 702(a)(5) of the Social Security Act, 42 U.S.C. 902(a)(5). Generally, the APA requires that an agency provide prior notice and opportunity for public comment before issuing a final rule. However, the APA provides exceptions to its notice and public comment procedures when an agency finds there is good cause for dispensing with such procedures because they are impracticable, unnecessary, or contrary to the public interest.

We have determined that good cause exists for dispensing with the notice and public comment procedures for this final rule. 5 U.S.C. 553(b)(B). Good cause exists because this final rule only extends the expiration date of the existing provisions. It makes no substantive changes to the current rule. The current regulations expressly provide that we may extend or terminate the current rule. Therefore, we have determined that opportunity for prior comment is unnecessary, and we are issuing this rule as a final rule.

In addition, for the reasons cited above, we find good cause for dispensing with the 30-day delay in the effective date of this final rule. 5 U.S.C. 553(d)(3). We are not making any substantive changes in our current rule, but are only extending the expiration date of the rule. For these reasons, we find it unnecessary to delay the effective date of our rule.

Executive Order 12866, as Supplemented by Executive Order 13563

We consulted with the Office of Management and Budget (OMB) and determined that this final rule does not meet the criteria for a significant regulatory action under Executive Order 12866, as supplemented by Executive Order 13563. Therefore, OMB did not review it.

We also determined that this final rule meets the plain language requirement of Executive Order 12866.

Regulatory Flexibility Act

We certify that this final rule will not have a significant economic impact on a substantial number of small entities because it affects individuals only. Therefore, the Regulatory Flexibility Act, as amended, does not require us to prepare a regulatory flexibility analysis.

Paperwork Reduction Act

The final rule does not create any new or affect any existing collections and, therefore, does not require Office of Management and Budget approval under the Paperwork Reduction Act.

(Catalog of Federal Domestic Assistance Program Nos. 96.001, Social Security—Disability 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 416

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

Carolyn W. Colvin,

Acting Commissioner of Social Security.

For the reasons stated in the preamble, we are amending subpart Q of part 404 and subpart J of part 416 of title 20 of the Code of Federal Regulations as set forth below:

¹ Pub. L. 114-74, section 832, 129 Stat. 584, 613. Section 832 of the BBA amends section 221(h) of the Social Security Act, 42 U.S.C. 421(h).

PART 404—FEDERAL OLD-AGE, SURVIVORS AND DISABILITY INSURANCE (1950—)

Subpart Q—[Amended]

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

Authority: Secs. 205(a), 221, and 702(a)(5) of the Social Security Act (42 U.S.C. 405(a), 421, and 902(a)(5)).

■ 2. Amend § 404.1615 by revising paragraph (c)(3) to read as follows:

§ 404.1615 Making disability determinations.

* * * * *

(c) * * *

(3) A State agency disability examiner alone if the claim is adjudicated under the quick disability determination process (see § 404.1619) or the compassionate allowance process (see § 404.1602), and the initial or reconsidered determination is fully favorable to you. This paragraph (c)(3) will no longer be effective on December 28, 2018 unless we terminate it earlier by publication of a final rule in the **Federal Register**; or

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

Subpart J—[Amended]

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

Authority: Secs. 702(a)(5), 1614, 1631, and 1633 of the Social Security Act (42 U.S.C. 902(a)(5), 1382c, 1383, and 1383b).

■ 4. Amend § 416.1015 by revising paragraph (c)(3) to read as follows:

§ 416.1015 Making disability determinations.

* * * * *

(c) * * *

(3) A State agency disability examiner alone if you are not a child (a person who has not attained age 18), and the claim is adjudicated under the quick disability determination process (see § 416.1019) or the compassionate allowance process (see § 416.1002), and the initial or reconsidered determination is fully favorable to you. This paragraph (c)(3) will no longer be effective on December 28, 2018 unless we terminate it earlier by publication of a final rule in the **Federal Register**; or

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 874

[Docket No. FDA-2016-N-3287]

Medical Devices; Ear, Nose, and Throat Devices; Classification of the Eustachian Tube Balloon Dilation System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the Eustachian tube balloon dilation system into class II (special controls). The special controls that will apply to the device are identified in this order and will be part of the codified language for the Eustachian tube balloon dilation system’s classification. The Agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

DATES: This order is effective October 24, 2016. The classification was applicable on September 16, 2016.

FOR FURTHER INFORMATION CONTACT: Joyce Lin, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2462, Silver Spring, MD, 20993-0002, 301-796-5544, Joyce.Lin@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of the regulations.

Section 513(f)(2) of the FD&C Act, as amended by section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144), provides two procedures by which a person may request FDA to classify a device under the criteria set forth in section 513(a)(1). Under the first procedure, the person submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified and, within 30 days of receiving an order classifying the device into class III under section 513(f)(1) of the FD&C Act, the person requests a classification under section 513(f)(2). Under the second procedure, rather than first submitting a premarket notification under section 510(k) of the FD&C Act and then a request for classification under the first procedure, the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence and requests a classification under section 513(f)(2) of the FD&C Act. If the person submits a request to classify the device under this second procedure, FDA may decline to undertake the classification request if FDA identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence with the device or if FDA determines that the device submitted is not of “low-moderate risk” or that general controls would be inadequate to control the risks and special controls to mitigate the risks cannot be developed.

In response to a request to classify a device under either procedure provided by section 513(f)(2) of the FD&C Act, FDA shall classify the device by written order within 120 days. This classification will be the initial classification of the device.

On December 17, 2015, Acclarent, Inc. submitted a request for classification of the ACCLARENT AERA™ Eustachian Tube Balloon Dilation System under section 513(f)(2) of the FD&C Act.

In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1). FDA classifies devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the request, FDA determined that the device can be classified into class II with the establishment of special controls. FDA