4.3.5 of the toy standard must comply with the third party testing requirements of section 14(a)(2) of the CPSA, unless listed in 16 CFR 1251.2.

(c) Section 108(a) of the CPSIA permanently prohibits any children's toy or child care article that contains concentrations of more than 0.1 percent of di-(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), or benzyl butyl phthalate (BBP). In accordance with section 108(b)(3) of the CPSIA, 16 CFR part 1307 prohibits any children's toy or child care article that contains concentrations of more than 0.1 percent of diisononyl phthalate (DINP), diisobutyl phthalate (DIBP), di-*n*-pentyl phthalate (DPENP), di-*n*-hexyl phthalate (DHEXP), or dicyclohexyl phthalate (DCHP). Materials used in children's toys and child care articles subject to section 108(a) of the CPSIA and 16 CFR part 1307 must comply with the third party testing requirements of section 14(a)(2) of the CPSA, unless listed in 16 CFR 1308.2.

§ 1252.2 Definitions.

In addition to the definitions given in sections 101, 106, and 108 of the CPSIA, the following definitions apply for this part 1252.

Post-consumer wood waste describes wood waste that is comprised of materials that are recovered from their original use and subsequently used in a new product. Examples of this type of waste include recycled demolition wood, packaging materials such as pallets and crates, used wood from landscape care (*i.e.,* from urban and highway trees, hedges, and gardens), discarded furniture, and waste wood from industrial, construction, and commercial activities.

Pre-consumer wood waste describes wood materials that have been recycled from an industrial process before being made available for consumer use. Examples of this type of waste include trimmings from engineered wood product (EWP) panel manufacturing, sawdust from cutting logs, or remaining wood pieces from sawing a log into framing lumber.

Unfinished means an EWP that does not have any surface treatments applied at manufacture, such as factory-applied coatings. Examples of such treatments may include paint or similar surface coating materials, wood glue, or metal fasteners, such as nails or screws.

Untreated means an EWP that does not have any additional finishes applied at manufacture. Examples of such finishes may include flame retardants or rot resistant finishes.

Virgin wood describes wood logs, fibers, chips, or layers that have not been recycled from a previous use.

§ 1252.3 Determinations for engineered wood products.

(a) The following engineered wood products do not exceed the lead content limits with a high degree of assurance as that term is defined in 16 CFR part 1107:

(1) Particleboard that is untreated and unfinished made from virgin wood or pre-consumer wood waste;

(2) Hardwood plywood that is untreated and unfinished made from virgin wood or pre-consumer wood waste; and

(3) Medium-density fiberboard that is untreated and unfinished made from virgin wood or pre-consumer wood waste.

(b) The following engineered wood products do not exceed the ASTM F963 elements solubility limits set forth in 16 CFR part 1250 with a high degree of assurance as that term is defined in 16 CFR part 1107:

(1) Particleboard that is untreated and unfinished made from virgin wood or pre-consumer wood waste;

(2) Hardwood plywood that is untreated and unfinished made from virgin wood or pre-consumer wood waste; and

(3) Medium-density fiberboard that is untreated and unfinished made from virgin wood or pre-consumer wood waste.

(c) The following engineered wood products do not exceed the phthalates content limits with a high degree of assurance as that term is defined in 16 CFR part 1107:

(1) Particleboard that is untreated and unfinished made from virgin wood or pre-consumer wood waste;

(2) Hardwood plywood that is untreated and unfinished made from virgin wood or pre-consumer wood waste and does not contain polyvinyl acetate (PVAc) adhesive formulations; and

(3) Medium-density fiberboard that is untreated and unfinished made from virgin wood or pre-consumer wood waste.

(d) Accessible component parts of children's products, children's toys, and child care articles made with EWPs, listed in paragraphs (a) through (c) of this section are not required to be third party tested pursuant to section 14(a)(2) of the CPSA and 16 CFR part 1107.

(e) Accessible component parts of children's products, children's toys, and child care articles made with engineered wood products not listed in paragraphs (a) through (c) of this section, or that contain post-consumer wood waste, are required to be third party tested pursuant to section 14(a)(2) of the CPSA and 16 CFR part 1107 and sections 101, 106, or 108 of the CPSIA, as applicable.

Alberta E. Mills,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2018–13392 Filed 6–21–18; 8:45 am]

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SOCIAL SECURITY ADMINISTRATION

20 CFR Parts 404 and 416

[Docket No. SSA–2018–0021]

RIN 0960–AI36

Extension of Sunset Date for Attorney Advisor Program

AGENCY: Social Security Administration.

ACTION: Final rule.

SUMMARY: We are extending for one year our rule authorizing attorney advisors to conduct certain prehearing proceedings and to issue fully favorable decisions. The current rule is scheduled to expire on August 3, 2018. In this final rule, we are extending the sunset date to August 2, 2019. We are making no other substantive changes.

DATES: This final rule is effective June 22, 2018.

FOR FURTHER INFORMATION CONTACT: Susan Swansiger, Office of Hearings Operations, Social Security Administration, 5107 Leesburg Pike, Falls Church, VA 22041, (703) 605–8500. For information on eligibility or filing for benefits, call our national toll-free number, 800–772–1213 or TTY 800–325–0778, or visit our internet site, Social Security Online, at *http://www.socialsecurity.gov*.

SUPPLEMENTARY INFORMATION:

Background of the Attorney Advisor Program

On August 9, 2007, we issued an interim final rule permitting some attorney advisors to conduct certain prehearing proceedings and issue fully favorable decisions when the documentary record warrants doing so. 72 FR 44763. We instituted this practice to provide more timely service to the increasing number of applicants for Social Security disability benefits and Supplemental Security Income payments based on disability. We considered the public comments we received on the interim final rule, and on March 3, 2008, we issued a final rule without change. 73 FR 11349. Under this rule, some attorney advisors may

develop claims and, in appropriate cases, issue fully favorable decisions before a hearing.

We originally intended the attorney advisor program to be a temporary modification to our procedures. Therefore, we included in sections 404.942(g) and 416.1442(g) of the interim final rule a provision that the program would end on August 10, 2009, unless we decided to either terminate the rule earlier or extend it beyond that date by publication of a final rule in the **Federal Register**. Since that time, we have periodically extended the sunset date (see 74 FR 33327 extending to August 10, 2011; 76 FR 18383 extending to August 9, 2013; 78 FR 45459 extending to August 7, 2015; 80 FR 31990 extending to August 4, 2017; and 82 FR 34400 extending to February 5, 2018). As we noted above, the current sunset date for the program is August 3, 2018. 83 FR 711.

Explanation of Extension

We published the final rule to adopt without change the interim final rule that we published on August 9, 2007. We stated our intent to monitor the program closely and to modify it if it did not meet our expectations. 73 FR 11349.

We explained in the 2008 final rule that the number of requests for hearings had increased significantly in recent years. From 2008 to the present, the number of pending hearing requests has continued to remain at a high level, and we anticipate that we will receive several hundred thousand hearing requests in fiscal year 2018 and in fiscal year 2019.[1] We are extending the program at this time while we continue to consider our options with respect to the program.

To preserve the maximum degree of flexibility and manage our hearings-level workloads effectively, we have decided to extend the attorney advisor rule until August 2, 2019. As before, we reserve the authority to end the program earlier, to extend it by publishing a final rule in the **Federal Register**, or to discontinue it altogether.

Regulatory Procedures

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

In addition, because we are not making any substantive changes to the existing rule, we find that there is good cause for dispensing with the 30-day delay in the effective date of a substantive rule provided by 5 U.S.C. 553(d)(3). To ensure that we have uninterrupted authority to use attorney advisors to address the number of pending cases at the hearing level, we find that it is in the public interest to make this final rule effective on the date of publication.

Executive Order 12866 as Supplemented by Executive Order 13563

We consulted with the Office of Management and Budget (OMB) and although we do not believe that this will be a significant regulatory action under Executive Order (E.O.) 12866, as supplemented by E.O. 13563, OMB has reviewed this final rule.

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

These rules do not create any new or affect any existing collections and, therefore, do 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.)

[1] Our budget estimates indicate that we expect to receive approximately 582,000 hearing requests in fiscal year 2018 and 578,000 in fiscal year 2019 (available at: *https://www.ssa.gov/budget/FY19Files/2019CJ.pdf*).

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).

Nancy A. Berryhill,

Acting Commissioner of Social Security.

For the reasons stated in the preamble, we are amending subpart J of part 404 and subpart N of part 416 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. In § 404.942, revise paragraph (g) to read as follows:

§ 404.942 Prehearing proceedings and decisions by attorney advisors.

* * * * *

(g) *Sunset provision.* The provisions of this section will no longer be effective on August 2, 2019, unless we terminate them earlier or extend them beyond that date by notice of a final rule in the **Federal Register**.

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

Subpart N—[Amended]

■ 3. The authority citation for subpart N 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).

■ 4. In § 416.1442, revise paragraph (g) to read as follows:

§ 416.1442 Prehearing proceedings and decisions by attorney advisors.

* * * * *

(g) *Sunset provision.* The provisions of this section will no longer be effective on August 2, 2019, unless we terminate them earlier or extend them beyond that date by notice of a final rule in the **Federal Register**.

[FR Doc. 2018–13359 Filed 6–21–18; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. FDA–2018–N–1929]

Medical Devices; Immunology and Microbiology Devices; Classification of the Next Generation Sequencing Based Tumor Profiling Test

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the next generation sequencing based tumor profiling test into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the next generation sequencing based tumor profiling test's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices, in part by reducing regulatory burdens.

DATES: This order is effective June 22, 2018. The classification was applicable on November 15, 2017.

FOR FURTHER INFORMATION CONTACT: Scott McFarland, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4676, Silver Spring, MD, 20993–0002, 301–796–6217, *Scott.McFarland@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the next generation sequencing based tumor profiling test as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as ''postamendments devices'' because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act to a predicate device that does not require premarket approval (see 21 U.S.C. 360c(i)). We determine whether a new device is substantially equivalent to a predicate by means of the procedures for premarket notification under section 510(k) of the FD&C Act and Part 807 (21 U.S.C. 360(k) & 21 CFR part 807, respectively).

FDA may also classify a device through ''De Novo'' classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act (21 U.S.C. 360c(f)(2)). Section 207 of the Food and Drug Administration Modernization Act of 1997 established the first procedure for De Novo classification (Pub. L. 105–115). Section 607 of the Food and Drug Administration Safety and Innovation Act modified the De Novo application process by adding a second procedure (Pub. L. 112–144). A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act (21 U.S.C. 360c(a)(1)). Although the device was automatically within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see 21 U.S.C. 360c(f)(2)(B)(i)). As a result, other device sponsors do not have to submit a De Novo request or PMA in order to market a substantially equivalent device (see 21 U.S.C. 360c(i), defining ''substantial equivalence''). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On September 25, 2017, Memorial Sloan-Kettering Cancer Center Department of Pathology submitted a request for De Novo classification of the MSK–IMPACT (Integrated Mutation Profiling of Actionable Cancer Targets). FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify 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 that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(B)). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on November 15, 2017, FDA issued an order to the requester classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 866.6080. We have named the generic type of device next generation sequencing (NGS) based tumor profiling test, and it is identified as a qualitative in vitro diagnostic test intended for NGS analysis of tissue