

Dated: May 21, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. FDA-2004-N-0258 (Formerly Docket No. 2004N-0456)]

RIN 0910-AF23

Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed at One-Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is extending the comment period for the proposed rule that appeared in the *Federal Register* of March 3, 2014. In the proposed rule, FDA requested comments on FDA's regulations for serving sizes for the Nutrition Facts Label. We are taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the proposed rule published on March 3, 2014 (79 FR 11990). Submit either electronic or written comments by August 1, 2014.

ADDRESSES: You may submit comments 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:

- Mail/Hand delivery/Courier (for paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name, Docket

No. FDA-2004-N-0258, and RIN 0910-AF23 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 the "Request for Comments" heading of the **SUPPLEMENTARY INFORMATION** section 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: Cherisa Henderson, Center for Food Safety and Applied Nutrition (HFS-830), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-5429, email: NutritionProgramStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the *Federal Register* of March 3, 2014 (79 FR 11990), we published a proposed rule entitled "Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed At One-Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments" with a 90-day comment period to request comments on amending the definition of a single-serving container; requiring dual-column labeling for certain containers; updating and modifying several reference amounts customarily consumed; adding several food products and food product categories to the reference amounts customarily consumed per eating occasion for the general food supply; amending the label serving size for breath mints; and making technical amendments to various aspects of the serving size regulations. Comments on the proposed rule will inform FDA's rulemaking to amend the regulations for serving sizes for the Nutrition Facts Label.

We received multiple requests for a 90-day extension of the comment period for the proposed rule. Each request conveyed concern that the original 90-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the proposed rule.

We have considered the requests and are extending the comment period for

the proposed rule for 60 days, until August 1, 2014. We believe that a 60-day extension allows adequate time for interested persons to submit comments without significantly delaying rulemaking on these important issues.

II. Request for Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: May 21, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF EDUCATION

34 CFR Chapter III

[Docket ID ED-2014-OSERS-0028; CFDA Number: 84.133B-1.]

Proposed Priority—National Institute on Disability and Rehabilitation Research—Rehabilitation Research and Training Centers

AGENCY: Office of Special Education and Rehabilitative Services, Department of Education.

ACTION: Proposed priority.

SUMMARY: The Assistant Secretary for Special Education and Rehabilitative Services proposes a priority for the Rehabilitation Research and Training Center (RRTC) Program administered by the National Institute on Disability and Rehabilitation Research (NIDRR). Specifically, this document proposes a priority for a RRTC on Vocational Rehabilitation Practices for Youth and Young Adults. We take this action to focus research attention on an area of national need. We intend for this priority to contribute to improved outcomes of youth and young adults with disabilities in the State Vocational Rehabilitation Services program.

DATES: We must receive your comments on or before June 26, 2014.

ADDRESSES: Submit your comments through the Federal eRulemaking Portal or via postal mail, commercial delivery, or hand delivery. We will not accept comments submitted by fax or by email or those submitted after the comment

period. To ensure that we do not receive duplicate copies, please submit your comments only once. In addition, please include the Docket ID at the top of your comments.

- *Federal eRulemaking Portal*: Go to www.regulations.gov to submit your comments electronically. Information on using Regulations.gov, including instructions for accessing agency documents, submitting comments, and viewing the docket, is available on the site under "Are you new to the site?"

- *Postal Mail, Commercial Delivery, or Hand Delivery*: If you mail or deliver your comments about these proposed regulations, address them to Patricia Barrett, U.S. Department of Education, 400 Maryland Avenue SW., Room 5142, Potomac Center Plaza (PCP), Washington, DC 20202–2700.

Privacy Note: The Department's policy is to make all comments received from members of the public available for public viewing in their entirety on the Federal eRulemaking Portal at www.regulations.gov. Therefore, commenters should be careful to include in their comments only information that they wish to make publicly available.

FOR FURTHER INFORMATION CONTACT: Patricia Barrett, U.S. Department of Education, 400 Maryland Avenue SW., Room 5142, Potomac Center Plaza (PCP), Washington, DC 20202–2700. Telephone: (202) 245–6211 or by email: patricia.barrett@ed.gov.

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION: This proposed priority is in concert with NIDRR's currently approved Long-Range Plan (Plan). The Plan, which was published in the **Federal Register** on April 4, 2013 (78 FR 20299), can be accessed on the Internet at the following site: www.ed.gov/about/offices/list/ose/nidrr/policy.html.

The Plan identifies a need for research and training in a number of areas. To address this need, NIDRR seeks to: (1) Improve the quality and utility of disability and rehabilitation research; (2) foster an exchange of research findings, expertise, and other information to advance knowledge and understanding of the needs of individuals with disabilities and their family members, including those from among traditionally underserved populations; (3) determine effective practices, programs, and policies to improve community living and participation, employment, and health

and function outcomes for individuals with disabilities of all ages; (4) identify research gaps and areas for promising research investments; (5) identify and promote effective mechanisms for integrating research and practice; and (6) disseminate research findings to all major stakeholder groups, including individuals with disabilities and their families in formats that are appropriate and meaningful to them.

This document proposes one priority that NIDRR intends to use for one or more competitions in fiscal year (FY) 2014 and possibly in later years. NIDRR is under no obligation to make an award under this priority. The decision to make an award will be based on the quality of applications received and available funding. NIDRR may publish additional priorities, as needed.

Invitation to Comment: We invite you to submit comments regarding this proposed priority. To ensure that your comments have maximum effect in developing the notice of final priority, we urge you to identify clearly the specific topic that each comment addresses.

We invite you to assist us in complying with the specific requirements of Executive Orders 12866 and 13563 and their overall requirement of reducing regulatory burden that might result from this proposed priority. Please let us know of any further ways we could reduce potential costs or increase potential benefits while preserving the effective and efficient administration of the program.

During and after the comment period, you may inspect all public comments about this proposed priority in Room 5142, 550 12th Street SW., PCP, Washington, DC, between the hours of 8:30 a.m. and 4:00 p.m., Washington, DC time, Monday through Friday of each week except Federal holidays.

Assistance to Individuals with Disabilities in Reviewing the Rulemaking Record: On request we will provide an appropriate accommodation or auxiliary aid to an individual with a disability who needs assistance to review the comments or other documents in the public rulemaking record for this document. If you want to schedule an appointment for this type of accommodation or auxiliary aid, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

Purpose of Program: The purpose of the Disability and Rehabilitation Research Projects and Centers Program is to plan and conduct research, demonstration projects, training, and related activities, including international activities, to develop methods, procedures, and rehabilitation

technology that maximize the full inclusion and integration into society, employment, independent living, family support, and economic and social self-sufficiency of individuals with disabilities, especially individuals with the most severe disabilities. This program is also intended to improve the effectiveness of services authorized under the Rehabilitation Act of 1973, as amended (Rehabilitation Act).

Rehabilitation Research and Training Centers

The purpose of the RRTCs, which are funded through the Disability and Rehabilitation Research Projects and Centers Program, is to achieve the goals of, and improve the effectiveness of, services authorized under the Rehabilitation Act through well-designed research, training, technical assistance, and dissemination activities in important topical areas as specified by NIDRR. These activities are designed to benefit rehabilitation service providers, individuals with disabilities, family members, policymakers and other research stakeholders. Additional information on the RRTC program can be found at: <http://www2.ed.gov/programs/rrtc/index.html>.

Program Authority: 29 U.S.C. 762(g) and 764(b)(2).

Applicable Program Regulations: 34 CFR part 350.

Proposed Priority

This document contains one proposed priority.

Vocational Rehabilitation Practices for Youth and Young Adults.

Background

Individuals with disabilities are less likely to be employed, or to participate in the labor force, than individuals without disabilities (U.S. Bureau of Labor Statistics, 2013). Similarly, youth and young adults with disabilities (age 16–24) are less likely than their peers without disabilities to be employed (U.S. Department of Labor, 2013). Compared to their peers without disabilities, youth and young adults with disabilities are also more likely to drop out of school (Chapman et al., 2011), less likely to participate in postsecondary education, (Newman et al., 2010; Newman et al., 2011; Wagner et al., 2005), and less likely to be employed after completing school (Wagner et al., 2005). Some groups of youth and young adults with disabilities are at increased risk for poor post-school employment outcomes, including those with mental illness or intellectual disabilities, and those from underserved

populations (Davies et al., 2009; Wagner et al., 2005).

From a policy perspective, improving the employment outcomes of youth and young adults with disabilities could decrease reliance on long-term public benefits. Research indicates that young adults with disabilities, especially those who receive Social Security Income (SSI) benefits before the age of 18, are at high risk of poor employment outcomes, low incomes, and continued reliance on public benefits (Davies et al., 2009; Fraker, 2011). The public cost of these benefits is high; in 2009, the combined cost of SSI benefits for youth age 13–25 was \$7.5 billion; the cost of Social Security Disability Insurance (SSDI) benefits to individuals under the age of 25 was greater than \$1 billion (Fraker, 2011).

The State Vocational Rehabilitation Services (VR) program administered by the Rehabilitation Services Administration (RSA) provides grants to States to support a wide range of services to assist individuals with disabilities prepare for and engage in gainful employment consistent with their strengths, resources, priorities, concerns, abilities, capabilities, interests, and informed choice. State reported data from RSA's Case Services Report (RSA-911) from FY 2012 show that youth and young adults age 14–24 accounted for 35 percent (about 113,850) of the total number of individuals whose service records were closed after receiving services from the VR program. However, RSA-911 data also show that 46 percent of these youth and young adults had not achieved an employment outcome at the time their service records were closed. The three most frequent reported reasons for their service record closure were: (1) Unable to contact or locate the client (36 percent), (2) refused services or further services (22 percent), and (3) failure to cooperate (22 percent). However, a recent study by Mathematica (Honeycutt et al., 2013) found wide variation in service patterns and outcomes among State VR agencies.

State VR agencies can play a critical role in helping youth and young adults attain their vocational goals, including collaborating with State and local education agencies to plan and provide services for students with disabilities. However, knowledge about best practices for VR agencies serving youth and young adults is insufficient given the persistent poor employment outcomes of youth and young adults with disabilities (Honeycutt et al., 2013). There are emerging practices that VR agencies may employ to assist youth and young adults to achieve

postsecondary goals. For example, some evidence-based secondary transition practices used in schools may be useful in VR settings (Test & Cease-Cook, 2012). In addition, a description of selected emerging transition practices, services, and models in State VR agencies is provided on RSA's "Emerging Practices" Web site (<http://rsa.ed.gov/emerging-practices.cfm>). The transition practices which are particularly appropriate to this age group, include interagency collaboration, career development activities, work experience, mentoring programs, shadowing programs, postsecondary education opportunities, and others. However, these activities vary in the degree to which their effectiveness in achieving successful outcomes for youth and young adults with disabilities is supported by research-based evidence (Cobb et al., 2013).

There is, therefore, a need to identify best practices that could be used by VR programs to improve outcomes for youth, especially those at high risk for poor outcomes. In addition, given the high proportion of youth and young adults who discontinue participation in the VR program, there is a need to understand the factors that may cause youth and young adults with disabilities to exit the VR program without an employment outcome and whether interventions can be implemented by the VR program to improve their outcomes.

References

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Definitions

For purposes of this priority, the stages of research are from the notice of final priorities and definitions published in the **Federal Register** on May 7, 2013 (78 FR 26513).

(i) *Exploration and Discovery* means the stage of research that generates hypotheses or theories by conducting new and refined analyses of data, producing observational findings, and creating other sources of research-based information. This research stage may include identifying or describing the barriers to and facilitators of improved outcomes of individuals with disabilities, as well as identifying or describing existing practices, programs,

or policies that are associated with important aspects of the lives of individuals with disabilities. Results achieved under this stage of research may inform the development of interventions or lead to evaluations of interventions or policies. The results of the exploration and discovery stage of research may also be used to inform decisions or priorities.

(ii) *Intervention Development* means the stage of research that focuses on generating and testing interventions that have the potential to improve outcomes for individuals with disabilities. Intervention development involves determining the active components of possible interventions, developing measures that would be required to illustrate outcomes, specifying target populations, conducting field tests, and assessing the feasibility of conducting a well-designed intervention study. Results from this stage of research may be used to inform the design of a study to test the efficacy of an intervention.

(iii) *Intervention Efficacy* means the stage of research during which a project evaluates and tests whether an intervention is feasible, practical, and has the potential to yield positive outcomes for individuals with disabilities. Efficacy research may assess the strength of the relationships between an intervention and outcomes, and may identify factors or individual characteristics that affect the relationship between the intervention and outcomes. Efficacy research can inform decisions about whether there is sufficient evidence to support “scaling-up” an intervention to other sites and contexts. This stage of research can include assessing the training needed for wide-scale implementation of the intervention, and approaches to evaluation of the intervention in real world applications.

(iv) *Scale-Up Evaluation* means the stage of research during which a project analyzes whether an intervention is effective in producing improved outcomes for individuals with disabilities when implemented in a real-world setting. During this stage of research, a project tests the outcomes of an evidence-based intervention in different settings. The project examines the challenges to successful replication of the intervention, and the circumstances and activities that contribute to successful adoption of the intervention in real-world settings. This stage of research may also include well-designed studies of an intervention that has been widely adopted in practice, but that lacks a sufficient evidence-base to demonstrate its effectiveness.

Proposed Priority

The Assistant Secretary for Special Education and Rehabilitative Services proposes a priority for an RRTC to conduct research on VR Practices for Youth and Young Adults. The RRTC must contribute to increased knowledge about effective VR practices that can improve employment outcomes of youth and young adults with disabilities by:

(a) Generating new knowledge that builds the evidence base of vocational rehabilitation practices, services, or models that improve the employment outcomes for youth and young adults. The center will conduct research to better understand the factors that affect the likelihood that youth and young adults are fully engaged in the VR program and achieve their vocational goals, i.e., completion of postsecondary education and training programs, and attainment of competitive employment, including research that—

(i) Identifies individual- and system-level factors that affect engagement and attainment of an employment outcome. Individual-level factors include, but are not limited to, demographic characteristics and impairment types and severity. System-level factors include, but are not limited to, financial disincentives to obtaining employment associated with other public programs and systems, characteristics and practices of VR State agencies, employer practices and perceptions, and macroeconomic conditions; and

(ii) Identifies the reasons for which youth and young adults with a disability discontinue their participation in the VR program before achieving successful postsecondary goals (e.g., postsecondary education or training) or employment outcomes.

(b) Conducting research to identify VR services and transition practices that increase the likelihood of youth and young adults with disabilities achieving successful employment outcomes. The research must also identify practices relevant to improving the outcomes of youth and young adults who are at particular risk for poor employment outcomes. Applicants must identify the specific at-risk group or groups of youth and young adults with disabilities they propose to include; provide evidence that the selected population or populations are, in fact, at risk for poor employment outcomes; and explain how the practices are expected to address the needs of the population or populations.

(c) Focusing its research on one or more specific stages of research. If the RRTC is to conduct research that can be categorized under more than one of the

research stages, or research that progresses from one stage to another, those research stages must be clearly specified. (These stages and their definitions are provided at end of the background statement section of this document.)

(d) Serving as a national resource center for youth and young adults with disabilities, their families, and other stakeholders, including other relevant grantees funded by the Office of Special Education and Rehabilitative Services. Specifically, this center must coordinate, as appropriate, with the OSEP-funded Parent Training and Information Centers, the OSEP-funded National Technical Assistance Center on Improving Transition and the RSA-funded Parent Information and Training Projects, and other relevant entities by conducting knowledge translation activities related to improving employment outcomes of youth and young adults that must, but are not limited to:

(i) Providing information and technical assistance to VR State agencies and related service providers, educators, employers, youth and young adults with disabilities and their representatives, families, and other key stakeholders.

(ii) Providing training, including graduate, pre-service, and in-service training, to educators, VR professionals, direct service professionals and related service providers, to facilitate a seamless and effective transition service delivery system. Training may be offered through conferences, workshops, public education programs, in-service training programs, and similar activities.

(iii) Disseminating research-based information and materials related to VR practices and services that increase employment for youth and young adults with disabilities.

(iv) Involving key stakeholder groups in the activities conducted under paragraphs (a) through (d) of this priority in order to maximize the relevance and usability of the new knowledge generated by the RRTC.

Types of Priorities

When inviting applications for a competition using one or more priorities, we designate the type of each priority as absolute, competitive preference, or invitational through a notice in the **Federal Register**. The effect of each type of priority follows:

Absolute priority: Under an absolute priority, we consider only applications that meet the priority (34 CFR 75.105(c)(3)).

Competitive preference priority: Under a competitive preference priority, we give competitive preference to an

application by (1) awarding additional points, depending on the extent to which the application meets the priority (34 CFR 75.105(c)(2)(i)); or (2) selecting an application that meets the priority over an application of comparable merit that does not meet the priority (34 CFR 75.105(c)(2)(ii)).

Invitational priority: Under an invitational priority, we are particularly interested in applications that meet the priority. However, we do not give an application that meets the priority a preference over other applications (34 CFR 75.105(c)(1)).

Final Priority

We will announce the final priority in a document in the **Federal Register**. We will determine the final priority after considering responses to this document and other information available to the Department. This document does not preclude us from proposing additional priorities, requirements, definitions, or selection criteria, subject to meeting applicable rulemaking requirements.

Note: This document does *not* solicit applications. In any year in which we choose to use this priority, we invite applications through a notice in the **Federal Register**.

Executive Orders 12866 and 13563

Regulatory Impact Analysis

Under Executive Order 12866, the Secretary must determine whether this regulatory action is “significant” and, therefore, subject to the requirements of the Executive order and subject to review by the Office of Management and Budget (OMB). Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action likely to result in a rule that may—

(1) Have an annual effect on the economy of \$100 million or more, or adversely affect a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities in a material way (also referred to as an “economically significant” rule);

(2) Create serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles stated in the Executive order.

This proposed regulatory action is not a significant regulatory action subject to review by OMB under section 3(f) of Executive Order 12866.

We have also reviewed this regulatory action under Executive Order 13563, which supplements and explicitly reaffirms the principles, structures, and definitions governing regulatory review established in Executive Order 12866. To the extent permitted by law, Executive Order 13563 requires that an agency—

(1) Propose or adopt regulations only upon a reasoned determination that their benefits justify their costs (recognizing that some benefits and costs are difficult to quantify);

(2) Tailor its regulations to impose the least burden on society, consistent with obtaining regulatory objectives and taking into account—among other things and to the extent practicable—the costs of cumulative regulations;

(3) In choosing among alternative regulatory approaches, select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity);

(4) To the extent feasible, specify performance objectives, rather than the behavior or manner of compliance a regulated entity must adopt; and

(5) Identify and assess available alternatives to direct regulation, including economic incentives—such as user fees or marketable permits—to encourage the desired behavior, or provide information that enables the public to make choices.

Executive Order 13563 also requires an agency “to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible.” The Office of Information and Regulatory Affairs of OMB has emphasized that these techniques may include “identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes.”

We are issuing this proposed priority only upon a reasoned determination that its benefits would justify its costs.

In choosing among alternative regulatory approaches, we selected those approaches that would maximize net benefits. Based on the analysis that follows, the Department believes that this proposed priority is consistent with the principles in Executive Order 13563.

We also have determined that this regulatory action would not unduly interfere with State, local, and tribal governments in the exercise of their governmental functions.

In accordance with both Executive orders, the Department has assessed the potential costs and benefits, both quantitative and qualitative, of this

regulatory action. The potential costs are those resulting from statutory requirements and those we have determined as necessary for administering the Department’s programs and activities.

The benefits of the Disability and Rehabilitation Research Projects and Centers Program have been well established over the years. Projects similar to the RRTCs have been completed successfully, and the proposed priorities will generate new knowledge through research. The new RRTCs will generate, disseminate, and promote the use of new information that would improve outcomes for individuals with disabilities in the areas of community living and participation, employment, and health and function.

Intergovernmental Review: This program is not subject to Executive Order 12372 and the regulations in 34 CFR part 79.

Accessible Format: Individuals with disabilities can obtain this document in an accessible format (e.g., braille, large print, audiotape, or compact disc) by contacting the Grants and Contracts Services Team, U.S. Department of Education, 400 Maryland Avenue SW., room 5075, PCP, Washington, DC 20202–2550. Telephone: (202) 245–7363.

If you use a TDD or TTY, call the FRS, toll free, at 1–800–877–8339.

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Dated: May 20, 2014.

Michael K. Yudin,

Acting Assistant Secretary for Special Education and Rehabilitative Services.

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