VII. Agency Contact

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

VIII. Other Information

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: April 21, 2015.

John Tschida,

Director, National Institute on Disability, Independent Living, and Rehabilitation Research.

[FR Doc. 2015–09598 Filed 4–23–15; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Final Priority; National Institute on Disability, Independent Living, and Rehabilitation Research; Disability and Rehabilitation Research Projects Program

AGENCY: Administration for Community Living, Department of Health and Human Services.

ACTION: Final priority.

CFDA Number: 84.133A–7.

SUMMARY: The Administrator of the Administration for Community Living announces a priority for the Disability and Rehabilitation Research Projects (DRRPs) Program administered by the National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR). Specifically, we announce a priority for a DRRP on Promoting Universal Design in the Built Environment. The Administrator of the Administration for Community Living may use this priority for competitions in fiscal year (FY) 2015 and later years. We take this action to focus research attention on an area of national need. We intend for this priority to contribute to strengthened evidence-base for UD standards and strategies and improved access to the built environment for individuals with disabilities.

DATES: *Effective Date:* This priority is effective May 26, 2015.

FOR FURTHER INFORMATION CONTACT: Marlene Spencer, U.S. Department of Health And Human Services, 400 Maryland Avenue SW., Room 5133, Potomac Center Plaza (PCP), Washington, DC 20202–2700. Telephone: (202) 245–7532 or by email: *marlene.spencer@acl.hhs.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:

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, and to improve the effectiveness of services authorized under the Rehabilitation Act of 1973, as amended (Rehabilitation Act).

Disability and Rehabilitation Research Projects

The purpose of NIDILRR's DRRPs, which are funded through the Disability and Rehabilitation Research Projects and Centers Program, is to improve the effectiveness of services authorized under the Rehabilitation Act by developing methods, procedures, and rehabilitation technologies that advance a wide range of independent living and employment outcomes for individuals with disabilities, especially individuals with the most significant disabilities. DRRPs carry out one or more of the following types of activities, as specified and defined in 34 CFR 350.13 through 350.19: research, training, demonstration, development, utilization, dissemination, and technical assistance.

An applicant for assistance under this program must demonstrate in its application how it will address, in whole or in part, the needs of individuals with disabilities from minority backgrounds (34 CFR 350.40(a)). The approaches an applicant may take to meet this requirement are found in 34 CFR 350.40(b). Additional information on the DRRP program can be found at: *www.ed.gov/rschstat/research/pubs/res-program.html#DRRP*.

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

Applicable Program Regulations: 34 CFR part 350.

We published a notice of proposed priority (NPP) for this program in the **Federal Register** on February 25, 2015 (80 FR 10099). That notice contained background information and our reasons for proposing the particular priority.

There are differences between the proposed priority and this final priority.

Public Comment: In response to our invitation in the notice of proposed priority, six parties submitted comments on the proposed priority.

Generally, we do not address technical and other minor changes. In addition, we do not address general comments that raised concerns not directly related to the proposed priority.

Analysis of the Comments and Changes: An analysis of the comments and of any changes in the priority since publication of the NPP follows.

Comment: Two commenters noted that research on the costs of, as well as the benefits of and savings from universal design (UD) applications, can facilitate future adoption of UD principles. These commenters suggested that the priority be revised to require such research on the costs and benefits of UD.

Discussion: Paragraph (a) requires research toward developing evidence-based practices for UD implementation. Research under this paragraph could include analysis of the costs, benefits, and savings associated with UD applications. Nothing in the priority precludes such research. NIDILRR does not wish to further specify the research requirements as suggested by the commenters and thereby limit the breadth of research topics proposed under this priority. However, we do agree that findings from analyses of the costs, benefits, and savings associated with UD implementation could help facilitate further adoption of UD principles into mainstream architecture and the development and construction of built environments.

Changes: We have modified the priority to include analyses of the costs, savings, and benefits of UD implementation as an optional activity that applicants may propose. The peer

review process will determine the merits of each proposal.

Comment: One commenter requested that NIDILRR refer to individuals with different abilities, instead of individuals with disabilities.

Discussion: NIDILRR aims to sponsor research that is directly applicable to, and serves, the needs of individuals with disabilities. While we understand that UD applications are intended to be beneficial to people with a wide range of different abilities, NIDILRR's aim is to generate new knowledge, products, and environments that can be used to provide full opportunities and accommodations for its citizens with disabilities. NIDILRR's applicants and stakeholders are accustomed to our focus on improving the outcomes of individuals with disabilities through research and development, and we think that we should be consistent in our terminology. Therefore we will continue to directly refer to people with disabilities as our primary stakeholders.

Changes: None.

Comment: One Commenter suggested that NIDILRR modify the priority to require the DRRP to engage in design and construction of practical and tangible physical projects that incorporate and demonstrate universal design concepts.

Discussion: NIDILRR's intended outcome of this DRRP is further adoption of universal design principles into mainstream architecture and the development and construction of built environments. We will contribute to this outcome by sponsoring research, training, technical assistance, as well as the development of new UD curricula and new UD standards and guidelines. Through these activities we will contribute to much wider implementation of universally designed facilities, outdoor environments, and housing. We do not intend the DRRP's limited resources to be used for the design or construction of a small number of universally designed projects.

Changes: None.

Comment: One commenter suggested that NIDILRR revise the priority to specify that Universal Design incorporates the concept of ''healthy indoor environmental quality'' (IEQ) to make buildings healthier for everyone and more accessible for people with chemical or electrical sensitivities.

Discussion: Nothing in the priority precludes applicants from including IEQ in its conceptualization of universal design, or in its work to facilitate the further adoption of universal design principles into the mainstream architecture and the development and construction of built environments. However, NIDILRR does not have a sufficient basis for further specifying the purposefully broad, long-standing principles of UD that the DRRP is intended to promote.

Changes: None.

Comment: One commenter recommended that NIDILRR modify the priority to include specific reference to the ''Goals of Universal Design,'' as published by Steinfeld and Maisel in 2012. This commenter suggested that these goals can be used by the DRRP to define and measure outcomes of UD practice and to frame the transfer of knowledge about UD into practice.

Discussion: The intended outcome of this priority is to expand UD practice into the mainstream of design, architecture, and construction of built environments. Nothing in the priority precludes applicants from using the ''Goals of Universal Design'' to frame or guide their work toward this outcome. However, NIDILRR does not wish to further specify the conceptual or measurement framework that is to be used by the DRRP, because we do not want to limit the breadth of approaches that various applicants may propose to meet this critical need. The peer review process will determine the merits of each proposal.

Changes: None.

Final Priority

The Administrator of the Administration for Community Living establishes a priority for a DRRP on Promoting Universal Design in the Built Environment.

The intended outcome of the DRRP on Universal Design is further adoption of universal design principles into mainstream architecture and the development and construction of built environments. The DRRP must contribute to this outcome by:

(a) Conducting research activities toward developing evidence-based practices for UD implementation in commercial and private facilities, outdoor environments, and housing. This research may include analyses of the costs, benefits, and savings associated with universal design implementation.

(b) Creating measurable UD standards and guidelines to facilitate the implementation of UD principles in commercial and private facilities, outdoor environments, and housing.

(c) Developing and promoting curricula on UD for university-level architecture, engineering, and design students.

(d) Providing training and technical assistance to designers, architects, and builders to incorporate UD principles and features into their buildings, projects, and communities.

(e) Providing training and technical assistance to NIDILRR's engineering and assistive technology grantees to incorporate UD strategies and standards into development projects serving the needs of individuals with disabilities and the broader population.

(f) Partnering with relevant stakeholders in carrying out all DRRP activities. Stakeholders include but are not limited to: individuals with disabilities, professional organizations that teach design principles, researchers, engineers, planners, designers, developers, architects, and builders.

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 (45 CFR 75).

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 (45 CFR 75); or (2) selecting an application that meets the priority over an application of comparable merit that does not meet the priority (45 CFR 75).

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 (45 CFR 75).

This notice does not preclude us from proposing additional priorities, requirements, definitions, or selection criteria, subject to meeting applicable rulemaking requirements.

Note: This notice 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 final 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 final 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 final priority only on a reasoned determination that its benefits justify its costs. In choosing among alternative regulatory approaches, we selected those approaches that maximize net benefits. Based on the analysis that follows, the Administration for Community Living (ACL), Department of Health and Human Services believes that this regulatory action is consistent with the principles in Executive Order 13563.

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

In accordance with both Executive orders, ACL 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 ACL's programs and activities.

The benefits of the Disability and Rehabilitation Research Projects and Centers Program have been well established over the years, as projects similar to the one envisioned by the final priority have been completed successfully, and the proposed priority will generate new knowledge through research. The new DRRP 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.

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You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: April 21, 2015.

John Tschida,

Director, National Institute on Disability, Independent Living, and Rehabilitation Research.

[FR Doc. 2015–09606 Filed 4–23–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–E–0130]

Determination of Regulatory Review Period for Purposes of Patent Extension; FLUBLOK

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for FLUBLOK and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human biological product.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov.* Submit written petitions (two copies are required) and written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit petitions electronically to *http://www.regulations.gov* at Docket No. FDA–2013–S–0610.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Management, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Campus, Rm. 3180, Silver Spring, MD 20993, 301–796–7900.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L.100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's