

Citizen Petition

Date: 05/07/2024

The undersigned submits this petition under Title 21 of the Code of Federal Regulations, Part 10.30 (Citizen Petitions) of the Federal Food, Drug, and Cosmetic Act to request the Commissioner of Food and Drugs to issue a new regulation.

A. Action Requested

- (1) Existing Regulation: There is currently no regulation classifying aging as a disease.
- (2) Proposed Regulation: The FDA shall promulgate a new regulation that defines aging as a disease for the purposes of research, treatment, and prevention.

Age Reversal Unity respectfully requests the FDA to:

1. Initiate proceedings to reclassify aging from a natural process to a disease for the purposes of regulation and research.
2. Review and consider the scientific and medical evidence presented in support of this reclassification.
3. Amend relevant FDA policies and regulations to reflect the reclassification of aging as a disease.

B. Statement of Grounds

1. Aging as the Underlying Cause of Chronic Diseases:

- Aging is the primary risk factor for a multitude of chronic diseases, including heart disease, cancer, Alzheimer's disease, and diabetes.
- The progressive deterioration of cellular function and physiological processes associated with aging significantly increases the risk of developing these debilitating conditions.
- The current healthcare model focuses on treating these diseases once they manifest, neglecting the root cause - aging itself.

2. Scientific Basis for Reclassification:

- Extensive research has identified nine hallmarks of aging, including cellular senescence, genomic instability, and telomere shortening. These hallmarks are targetable cellular processes that contribute to age-related decline.
- Studies on model organisms demonstrate the feasibility of intervening in these hallmarks of aging, extending healthy lifespans.
- The growing body of knowledge on the biology of aging is paving the way for developing therapies that target the root causes of age-related diseases.

3. Benefits of Redefining Aging as a Disease:



- Increased research funding for interventions aimed at slowing or preventing age-related decline.
- Improved access to preventative measures targeting the biology of aging.
- A shift in healthcare focus from treating age-related diseases reactively to promoting healthy aging proactively.

4. Addressing Potential Drawbacks:

- The FDA should establish clear guidelines to differentiate normal aging from pathological aging processes.
- Streamlined pathways for therapies targeting aging mechanisms should be implemented to address potential regulatory hurdles.

C. Environmental Impact

A claim for categorical exclusion under § 25.32 of this chapter applies. This petition for rulemaking is unlikely to have a significant environmental impact. The development of interventions targeting aging might have future environmental implications, but those would be assessed during the development and approval process for each specific therapy.

D. Economic Impact

Not applicable at this stage. We are prepared to submit an economic impact statement if requested by the Commissioner following review of the petition.

E. Certification

The undersigned certifies, to the best knowledge and belief of the undersigned, that this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Signature: 

Age Reversal Unity

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