Alliance FOR AGING RESEARCH
Catalyzing Innovation for Healthy Aging

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Dockets Management Staff (HFA-305),
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Docket No. FDA-2020-D-1621 for "Geriatric Information in Human Prescription Drug and Biological Product Labeling"

Dr. Marks and Dr. Cavazzoni,

The Alliance for Aging Research (the "Alliance") is the leading non-profit organization dedicated to accelerating the pace of scientific discoveries and their application to improve the experience of aging and health. The Alliance believes that advances in research help people live longer, happier, more productive lives, and reduce health care costs over the long term.

The Alliance would like to express our sincere appreciation to the U.S. Food and Drug Administration (FDA) for issuing updated draft guidance on labeling information specific to geriatric patients for human drugs and biologics. The previous guidance document was issued in 2001. A critical aspect of caring for older adults is optimizing and facilitating adherence with prescribed medications. Eighty-nine percent of adults ages 65 and older take a prescription medication and more than half of adults in this age group use four or more prescription drugs.[1] Prescribing drugs for older adults also has unique challenges. The pharmacokinetics and pharmacodynamics of many medications can have age-related differences.

This update of the draft guidance on geriatric labeling is a critical step toward improving the appropriate prescribing of medication to older adults. The Alliance supports the efforts of the FDA to create new older adult-specific guidance, such as its Inclusion of Older Adults in Cancer Clinical Trials document.

[1] Neuman, Tricia, and Ashley Kirzinger. "Data Note: Prescription Drugs and Older Adults." KFF, Kaiser Family Foundation, 9 Aug. 2019, www.kff.org/health-reform/issue-brief/data-note-prescription-drugs-and-older-adults/.

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Prescription labeling information must include data specific to older adults that are early understood by both prescribers and patients to guide safe and effective use.

Geriatric Patients are Not a "Homogenous Group"

The draft guidance clarifies that the Geriatric Use subsection in human drug and biologic labeling should include data for patients aged 65 and older. We appreciate that the agency explicitly states that "patients 65 years of age and older are not a homogeneous group," and that labeling should include important differences relevant to subgroups of older adults. Metabolism and immune system responses change with increasing age. The rate of decline, the onset of comorbidities, and the use of medications vary from person to person and functional status widely differs through the biological aging process. In particular, the aging process can change the clinical characteristics of an adult as they transition from the "youngest-old" to the "oldest-old." Including data from reportable studies on these differences is essential for the optimal treatment of older adults and avoiding adverse drug events.

We agree that labeling should include specific information on older adult age subgroups when appropriate (e.g., 65-74 years of age, 75-84 years of age, and 85 years of age or older.) Furthermore, we emphasize the importance of ensuring labeling includes data on the percentage and the total number of older adult patients included in clinical trials for a drug. This information should also include detail by age subgroup (i.e., 65 years and older, 75 years and older).

Non-RCT Information

The draft guidance states that information in the Geriatric Use subsection may come from "other reported clinical experiences." Examples in this category include but are not limited to clinical registries, well-documented studies, case studies, adverse event reports, and other types of post-market surveillance studies. Older adults are often underrepresented in pre-market clinical trials and data. Therefore, post-market studies are an essential source of data for understanding the safety and efficacy of given prescription medication for this population but are too often not published or publicly reported. The Alliance requests clarity on the types of non-randomized clinical trial (RCT) data eligible for inclusion in the Geriatric Use subsection.

The primary purpose of prescription drug labeling is to provide information to healthcare professionals. However, we believe it would be useful for the FDA to provide additional information to aid in the patient interpretation of labeling data. Labeling can often be difficult to read and understand. Most individuals are not familiar with the various types of clinical and real-world data that inform prescription drug labeling. To support transparency and empower patients, we recommend the FDA include information online to explain to older adults how to interpret non-RCT data and understand the sources of these data.

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Positioning of Information

Older adults are the age group at the greatest risk for experiencing medication errors as, on average, they are prescribed more medications than younger cohorts. Critical differences in the effectiveness and safety of a drug can present for older individuals in comparison to younger adults. Information on age-related differences in effectiveness, dose-response, and safety should be easily identified. Additionally, not filling, delaying, or curtailing the use of prescription medications can have life-threatening consequences. Labeling information for healthcare providers should include adverse event information regarding changes in prescribed use.

The Alliance agrees that geriatric information should be included in multiple sections of a drug label when relevant. For example, differences detected in the safe dosage amount for older adults compared to younger adults should be included in both the geriatric use subsection and the dosing information sections of the labeling. It is critically important that labeling supports the ability of prescribing healthcare professionals to easily recognize important clinical differences in a product between different age groups.

Conclusion

Thank you for the opportunity to provide comments on the agency's draft guidance document, "Geriatric Information in Human Prescription Drug and Biological Product Labeling." If you have any questions, please do not hesitate to contact us. Inquiries can be directed to the Alliance for Aging Research's Director of Public Policy, Michael Ward, at mward@agingreach.org.

Sincerely,

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