FDA Statement on Advancing Access to Nonprescription Drugs

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At the FDA, we're continuing to look at ways we can foster greater access to the medicines that help keep people healthy. We are considering all options for positively impacting both access and the cost of health care, and today we are announcing a new effort to establish innovative approaches to increase access to a broader selection of nonprescription drug products for consumers, empowering them to self-treat common conditions and potentially some chronic conditions.

While the FDA doesn't have a direct role in the cost of medicines, we're very mindful of the time and financial cost to patients and the health care system to fill a prescription medicine – particularly one taken repeatedly for chronic conditions. Our hope is that the steps we're taking to advance this new, more modern framework will contribute to lower costs for our health care system overall and provide greater efficiency and empowerment for consumers by increasing the availability of certain products that would otherwise be available only by prescription. Clearly, not all prescription drugs can or should be available directly to consumers. Many require a professional diagnosis and oversight to ensure the benefits of use outweigh the risks. But other, select types of drugs, are appropriate for nonprescription use if we are able to ensure access to resources that will help patients determine if the medicine is right for them. These are the products that we will carefully consider for this innovative pathway.

These approaches include applying innovative tools, like digital health technologies, that would support consumers in appropriately and safely self-selecting and using certain drugs. For example, imagine a set of questions answered on a mobile medical application ("app") that helps someone determine (self-select) whether the use of a nonprescription drug is appropriate for them prior to being able to purchase that drug, or new types of drug labeling, in addition to the current labeling that's already required for nonprescription drug products.

Nonprescription drug products are used by consumers without the supervision of a health care professional and require a very high safety margin that takes into consideration the potential consequences of inappropriate use, the ability of the consumer to determine that they have the condition for which the drug is to be used, and the expected effectiveness of the product when

used under nonprescription conditions. Consumers may recognize the “Drug Facts Labeling” (DFL) on nonprescription drug packaging as the primary source for information about a product’s intended use, directions for use and important safety information, all designed in understandable language that is tested for consumer comprehension. As we look at expanding the types of products available without a prescription, the safety of patients remains a top priority.

We envision this process will work as follows – a sponsor, for example one that has a prescription cholesterol-lowering drug or a prescription naloxone product, could develop one of these innovative approaches to increase the likelihood of correct self-selection and accurate use of their product in the nonprescription setting. After performing appropriate studies demonstrating that the novel approach works as intended, in other words, that consumers can safely use the drug without a prescription and associated supervision of a health care professional, the sponsor could submit an application for FDA consideration for nonprescription status for the product.

Currently, nonprescription drugs can be marketed under either of two regulatory pathways: the Over-the-Counter (OTC) Drug Review (OTC Monograph Process) or the New Drug Application (NDA) process, and there are different requirements under each system. Today’s new FDA draft guidance, Innovative Approaches for Nonprescription Drug Products, applies to drugs under the NDA process and is intended to extend that NDA pathway to include therapeutic indications that have not, historically, been available for use without a prescription.

This draft guidance outlines two innovative approaches for demonstrating safety and effectiveness that may be useful to consider in cases where the DFL alone is not sufficient to ensure that the drug product can be used safely and effectively in a nonprescription setting. The first is the development of labeling in addition to the DFL. The second approach is the implementation of additional conditions so that consumers appropriately self-select and use the product. Either of these approaches could involve the use of technology, such as mobile apps or other tools. The appropriateness and specific details of either of these approaches will depend on the circumstances that apply to a particular drug product.

But it’s important we’re clear that we are not proposing a change in the evidentiary standard needed for a product to be approved by the FDA as nonprescription. As we move into making this a reality, the FDA will ensure that products considered under this framework receive a robust scientific review to ensure they can be used safely by patients. The innovative approaches described in this draft guidance could lead to the approval of a wider range of nonprescription drug products, including drug products that may treat chronic conditions, in ways that maintain the FDA’s gold standard for safety and effectiveness. This will require coordination and collaboration with industry and other stakeholders to strike the right balance of access while protecting public health and we’re committed to a public process that allows for input from a broad range of voices on the impact of this proposed policy.

We see today’s draft guidance as a first step as drug developers begin to study products that might be considered for marketing without a prescription. As noted in the Spring 2018 Unified Agenda of Regulatory and Deregulatory Actions, we intend to continue this effort with proposed

rulemaking in the near future and will provide additional information as we move forward. The proposed rule will clarify the requirements for a drug product that could be marketed as a nonprescription drug product with a requirement that ensures appropriate self-selection by consumers, appropriate actual use, or both, in order to obtain the drug without a prescription.

Our ultimate goal with modernizing our regulatory framework for nonprescription drugs is to help facilitate a market that is more competitive, enables greater access to medical products, empowers consumers in their health care decisions, and provides more affordable options for Americans.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation’s food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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