Innovative Approaches for Nonprescription Drug Products

Guidance for Industry

DRAFT GUIDANCE

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For questions regarding this draft document, contact (CDER) Chris Wheeler at 301-796-0151.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

July 2018
OTC

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I. INTRODUCTION

This guidance describes two innovative approaches that may be useful to consider for demonstrating safety and effectiveness for a nonprescription drug product in cases where the drug facts labeling (DFL) alone is not sufficient to ensure that the drug product can be used safely and effectively in a nonprescription setting: (1) the development of labeling in addition to the DFL, and (2) the implementation of additional conditions so that consumers appropriately self-select and use the product.

The appropriateness and specific details of either of these approaches will depend on the circumstances that apply to a particular drug product.

These innovative approaches may be useful for applicants intending to develop and seek approval of certain nonprescription drug products through the submission of a new drug application (NDA), including an application submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355).[2]

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

[1] This guidance has been prepared by the Office of Medical Policy in the Center for Drug Evaluation and Research at the Food and Drug Administration at the Food and Drug Administration.

[2] The recommendations on the innovative approaches presented in this guidance may also be appropriate for combination products (as defined at 21 CFR 3.2(e)) subject to review under a new drug application (NDA).

II. BACKGROUND

FDA approves new drugs[3] as prescription or nonprescription drug products under section 505 of the FD&C Act (21 U.S.C. 355). A drug product must be dispensed by prescription if it is not safe to use except under the supervision of a practitioner licensed by law to administer the drug (*health care practitioner*) (see section 503(b)(1) of the FD&C Act (21 U.S.C. 353(b)(1)). If a drug product does not meet the criteria for prescription-only dispensing, it may be marketed as a nonprescription drug product.

FDA determines whether the information submitted as part of a new drug application (NDA) for a nonprescription drug product is sufficient to ensure that the drug product is safe and effective for nonprescription use under the conditions prescribed, recommended, or suggested in its proposed labeling (see sections 505(d) and 503(b)(1) of the FD&C Act (21 U.S.C. 355(d) and 353(b)(1)). Studies regarding self-selection and actual use can help demonstrate that the drug product is safe and effective for use without the supervision of a health care practitioner. Self-selection studies test whether consumers can apply information in the drug product's labeling to their personal medical situations and make correct decisions to use or not use the drug product, and actual use studies provide information on how consumers will use the drug product.[4]

Nonprescription drug products must comply with applicable labeling requirements for over-the-counter (OTC) drug products under 21 CFR part 201, including, but not limited to, the format and content requirements for OTC drug product labeling under § 201.66. Labeling created to satisfy the requirements in § 201.66 is commonly referred to as the DFL. The DFL is intended to enable consumers to appropriately self-select and use the nonprescription drug product safely and effectively. In instances where the DFL alone would not be sufficient, an applicant may consider proposing innovative approaches, in addition to the DFL, to ensure that the drug product is safe and effective for use as a nonprescription drug product.

FDA believes the innovative approaches described in this guidance could lead to the approval of a wider range of nonprescription drug products, including drug products that may treat chronic conditions or other conditions for which the limitations of the DFL present challenges for adequate communication of information needed for safe and effective use without the supervision of a health care practitioner. Approval of a wider range of nonprescription drug products has the potential to improve public health by increasing the types of drug products consumers can access and use that would otherwise only be available by prescription.

[3] The term *new drug* is defined at section 201(p) of the FD&C Act (21 U.S.C. 321(p)).

[4] See the guidance for industry *Self-Selection Studies for Nonprescription Drug Products*. We update guidances periodically. For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

III. INNOVATIVE APPROACHES FOR NONPRESCRIPTION DRUG PRODUCTS

A. Labeling in Addition to the DFL for Nonprescription Drug Products

In addition to labeling created to satisfy the DFL requirements,[5] FDA may approve additional labeling for nonprescription drug products (see section 505(d) of the FD&C Act (21 U.S.C. 355(d)). Examples of nonprescription drug product labeling the Agency may consider approving in addition to the DFL include, but are not limited to, the following:

- Information leaflets or other documents contained inside the carton or container for the nonprescription drug product
- Text or images on a video display, including interactive displays for consumers to review
- Information displayed on websites
- Statements or questions in a mobile application

B. Nonprescription Drug Products With Additional Conditions for Safe and Effective Use

Applicants may consider proposing one or more additional conditions that consumers must fulfill to ensure that the drug product is safe and effective for nonprescription use, when labeling alone is not sufficient for this purpose.

Examples of additional conditions for safe and effective use that the Agency may consider, particularly with regard to appropriate self-selection and actual use, include, but are not limited to, the following:

- Prior to purchase, the consumer is required to respond to a set of questions on a self-selection test in a mobile application, and the outcome of the self-selection test affirmatively indicates that the consumer is an appropriate candidate to use the nonprescription drug product.
- Prior to purchase, the consumer is required to view and affirm that they viewed text or images in a video that describes how to appropriately use the nonprescription drug product.

As part of the development process for a nonprescription drug product for which an additional condition for nonprescription use will be proposed, applicants should consider how to ensure proper implementation of any additional condition necessary for safe and effective use.

[5] 21 CFR 201.66

We encourage applicants to meet with FDA staff to discuss any questions that arise during the development of a nonprescription drug product for which an additional condition for safe and effective use will be proposed.