
Innovative Approaches for Nonprescription Drug Products

Guidance for Industry

DRAFT GUIDANCE

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

**July 2018
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**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)**

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1 **Innovative Approaches for Nonprescription Drug Products**
2 **Guidance for Industry¹**
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5 This draft guidance, when finalized, will represent the current thinking of the Food and Drug
6 Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not
7 binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the
8 applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible
9 for this guidance as listed on the title page.
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14 **I. INTRODUCTION**
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16 This guidance describes two innovative approaches that may be useful to consider for
17 demonstrating safety and effectiveness for a nonprescription drug product in cases where the
18 drug facts labeling (DFL) alone is not sufficient to ensure that the drug product can be used
19 safely and effectively in a nonprescription setting: (1) the development of labeling in addition to
20 the DFL, and (2) the implementation of additional conditions so that consumers appropriately
21 self-select and use the product.
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23 The appropriateness and specific details of either of these approaches will depend on the
24 circumstances that apply to a particular drug product.
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26 These innovative approaches may be useful for applicants intending to develop and seek
27 approval of certain nonprescription drug products through the submission of a new drug
28 application (NDA), including an application submitted pursuant to section 505(b)(2) of the
29 Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355).²
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31 In general, FDA’s guidance documents do not establish legally enforceable responsibilities.
32 Instead, guidances describe the Agency’s current thinking on a topic and should be viewed only
33 as recommendations, unless specific regulatory or statutory requirements are cited. The use of
34 the word *should* in Agency guidances means that something is suggested or recommended, but
35 not required.
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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).

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38 **II. BACKGROUND**

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40 FDA approves new drugs³ as prescription or nonprescription drug products under section 505 of
41 the FD&C Act (21 U.S.C. 355). A drug product must be dispensed by prescription if it is not
42 safe to use except under the supervision of a practitioner licensed by law to administer the drug
43 (*health care practitioner*) (see section 503(b)(1) of the FD&C Act (21 U.S.C. 353(b)(1))). If a
44 drug product does not meet the criteria for prescription-only dispensing, it may be marketed as a
45 nonprescription drug product.

46
47 FDA determines whether the information submitted as part of a new drug application (NDA) for
48 a nonprescription drug product is sufficient to ensure that the drug product is safe and effective
49 for nonprescription use under the conditions prescribed, recommended, or suggested in its
50 proposed labeling (see sections 505(d) and 503(b)(1) of the FD&C Act (21 U.S.C. 355(d) and
51 353(b)(1))). Studies regarding self-selection and actual use can help demonstrate that the drug
52 product is safe and effective for use without the supervision of a health care practitioner. Self-
53 selection studies test whether consumers can apply information in the drug product's labeling to
54 their personal medical situations and make correct decisions to use or not use the drug product,
55 and actual use studies provide information on how consumers will use the drug product.⁴

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

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

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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>.

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75 **III. INNOVATIVE APPROACHES FOR NONPRESCRIPTION DRUG PRODUCTS**

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

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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:

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- 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

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

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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.

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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:

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- 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.

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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

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