

UNITED STATES FOOD & DRUG ADMINISTRATION

Format and Content Requirements for Over-the-Counter Drug Product Labeling

OMB Control No. 0910-0340

REQUEST FOR NON-SUBSTANTIVE, NON-MATERIAL CHANGE:

The FDA's legal authority to modify and simplify the manner in which certain information is presented in over-the-counter (OTC) drug product labeling derives from sections 201, 502, 503, 505, and 701 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act). Drugs known as OTC monograph drugs may be marketed without an approved drug application under section 505 if they satisfy section 505G of the FD&C Act, as well as other applicable requirements. Agency regulations in § 201.66 (21 CFR 201.66) establish standardized content and format requirements for the labeling of all marketed OTC drug products; require that OTC drug product labeling include uniform headings and subheadings; and require that labeling be presented in a standardized order, with minimum standards for font size and other graphical features. Currently marketed OTC drug products are required to comply with these labeling requirements.

Enacted March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) reforms the way certain nonprescription, OTC drugs are regulated in the United States. Among other provisions, the CARES Act adds section 744M to the FD&C Act and establishes an OTC monograph drug user fee program (OMUFA) by which FDA will assess and collect fees applicable to those who submit OTC Monograph Order Requests (OMORS). As with similar programs, the user fees are intended to support important agency activities by providing additional resources intended to reduce review times associated with product submission requirements. In accordance with the CARES Act and to help implement applicable provisions, we plan to publish a notice in the Federal Register to establish fees with respect to OTC monograph drug facilities and OMORS for FY 2021 upon enactment of the necessary appropriation, expected in December 2020. The OTC monograph drug facility fees for FY 2021 will be due 45 days after publication of the notice. We have developed proposed Form FDA 5009 to facilitate the submission of fees. Form FDA 5009 entitled, "*OVER-THE-COUNTER MONOGRAPH USER FEE COVER SHEET*," collects the minimum information necessary to determine whether a fee is required for the review of an OMORS or for payment of a facility fee, and enables FDA to assess, account for, and track OTC user fees. We estimate an additional 575 burden hours to the information collection resulting from use of Form FDA 5009. Upon implementation of the program we intend to offer an estimate of the anticipated number of respondents. Although section 3581(o) of the CARES Act reads: *Chapter 35 of title 44, United States Code, shall not apply to collections of information made under this section [“OTC drug review”]*, we are requesting OMB review and approval for the user fee collection instrument, proposed Form FDA 5009, as a non-substantive change within this collection.

Information in this request may be found along with other details regarding the OTC user fee program on our website at <https://www.fda.gov/industry/fda-user-fee-programs/over-counter-monograph-user-fee-program-omufa>.

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