

UNITED STATES FOOD & DRUG ADMINISTRATION

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

OMB Control Nos. 0910-0340 and 0910-0641

Request for Non-substantive Change and Request to Discontinue:

Public Law 109-462, the Dietary Supplement and Nonprescription Drug Consumer Protection Act (the DSNDCPA), enacted on December 22, 2006, added new section 502(x) of the Federal Food Drug and Cosmetic Act (FD&C Act) (21 U.S.C. 352(x)). The DSNDCPA amended the FD&C Act to add reporting, recordkeeping, and labeling requirements for nonprescription (over-the-counter (OTC)) drug products that are marketed without an approved application under section 505 of the FD&C Act (21 U.S.C. 355). Statutory provisions in section 502(x) of the FD&C Act prohibit the misbranding of OTC drugs and govern content and format requirements for drug product labeling. Section 502(x) of the FD&C Act requires the label of a nonprescription drug product marketed without an approved application in the United States to include a domestic address or domestic telephone number through which a manufacturer, packer, and distributor may receive a report of a serious adverse event associated with the product.

Section 760 of the DSNDCPA (21 U.S.C. 379aa) provides for mandatory safety reporting for OTC human drug products not subject to applications approved under section 505 of the FD&C Act (new drug applications (NDAs) or abbreviated new drug applications (ANDAs)). Accordingly, the 21 U.S.C. 379aa requirements apply to all OTC drug products marketed without an approved application, including those marketed under the OTC Drug Monograph Review process (whether or not subject to a final monograph) and those marketed outside the monograph system. To help implement these provisions and communicate FDA's thinking in this regard, we developed the guidance document entitled "*Labeling of Nonprescription Human Drug Products Marketed without an Approved Application as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act: Questions and Answers*," (September 2009), available from our website at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/labeling-nonprescription-human-drug-products-marketed-without-approved-application-required-dietary>. Information collection discussed in the guidance is currently approved under OMB control number 0910-0641.

For efficiency of agency operations, we are consolidating burden we attribute to the reference guidance document to information collection associated with the statutory and regulatory requirements currently approved in OMB control number 0910-0340. Accordingly, we have adjusted the estimated burden in OMB control number 0910-0340 by 900 responses and 3,600 hours annually to reflect this change. Publication of a 60-day notice soliciting public comment on all elements of the information collection, including the consolidation and burden adjustments, is currently underway. Upon approval of this request, we intend to discontinue OMB control number 0910-0641.

Dated: December 2021